PUBLIC PACKET

May 20, 2021 - Alaska Board of Pharmacy Meeting - Day 1

May 20, 2021 9:00 AM AKDT

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STATE OF ALASKA

Department of Commerce, Community, and Economic Development
Professional Licensing

ALASKA BOARD OF PHARMACY

May 20 - 21, 2021

Teleconference/Videoconference

Board Packet

PUBLIC PACKET

State of Alaska 2021 HOLIDAY CALENDAR

State Holidays

Date	Holiday
01/01/2021	New Year's Day
01/18/2021	MLK Jr.'s Birthday
02/15/2021	Presidents' Day
03/29/2021	Seward's Day
05/31/2021	Memorial Day
07/04/2021	Independence Day (observed 07/05/2021)
09/06/2021	Labor Day
10/18/2021	Alaska Day
11/11/2021	Veterans' Day
11/25/2021	Thanksgiving Day
12/25/2021	Christmas Day (observed 12/24/2021)
01/01/2022	New Year's Day (observed 12/31/2021)

Please refer to appropriate collective bargaining unit agreement for more information regarding holidays.

Holiday

JANUARY

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FEBRUARY

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NOVEMBER

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DECEMBER

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Alaska Board of Pharmacy Roster

Board Member Name	Initial Appointment	Reappointed	Term End
Richard Holt, PharmD, MBA (Chair)	03/01/2016	03/01/2020	03/01/2024
Leif Holm, PharmD (Vice Chair)	03/01/2015	03/01/2019	03/01/2023
Lana Bell, RPh (Secretary)	05/31/2016	03/01/2018	03/01/2022
James Henderson, RPh	03/01/2017	03/01/2017	03/01/2025
Justin Ruffridge, PharmD	03/01/2020		03/01/2024
Tammy Lindemuth (Public Member)	01/24/2018	03/01/2018	03/01/2025
Sharon Long (Public Member)	03/01/2018		03/01/2022

Updated 02/10/2021

AGENDA

ALASKA BOARD OF PHARMACY MEETING

TENTATIVE AGENDA

MAY 20, 2021 – DAY 1

Call-in Number: +12532158782
Pin: 97392133993#, Code: 296746

Discussion of the following topics may require executive session. Only authorized members will be permitted to remain in the Zoom room during executive session.

Board Members:

Richard Holt, *PharmD, MBA (Chair)*

Leif Holm, *PharmD (Vice Chair)*

James Henderson, *RPh*

Lana Bell, *RPh (Secretary)*

Justin Ruffridge, *(PharmD)*

Tammy Lindemuth, *Public Member*

Sharon Long, *Public Member*

Staff:

Laura Carrillo, *Executive Administrator*

Lisa Sherrell, PDMP *Program Coordinator*

Heather Noe, *Occupational Licensing Examiner*

Bethany Carlile, *Occupational Licensing Examiner*

Upcoming Zoom Meetings:

September TBD

Meeting Details

Meeting Name: May 20, 2021 - Alaska Board of Pharmacy Meeting - Day 1

Meeting Start Time: 9:00 AM AKDT

Meeting Start Date: 05/20/2021

Meeting End Time: 4:30 PM AKDT

Meeting End Date: 05/20/2021

Meeting Location: Videoconference via Zoom

Meeting Registration Link:

https://zoom.us/meeting/register/tJMufuuprTgjE9eCSo9FtxXcl0nsgPSiEF4Z

Agenda

I. Agenda Item #1 – 9:00 a.m. Roll Call/Call to Order (Chair Holt)
II. Agenda Item #2 – 9:02 a.m. Review/Approve Agenda (Chair Holt)
III. Agenda Item #3 – 9:05 a.m. Ethics Disclosures (Chair Holt)
IV. Agenda Item #4 – 9:10 a.m. Review/Approve Meeting Minutes (Chair Holt)
V. Agenda Item #5 – 9:15 a.m. PDMP Update (Lisa Sherrell/Laura Carrillo)
    A. PDMP – Pharmacy Report
    B. Database/Grant updates
    C. Resources (zero reporting video & dispenser guide)

D. Compliance monitoring/Disciplinary matrix

VI. Agenda Item #6 – 9:45 a.m. Investigative Update (Michael Bowles)

A. Investigative report

B. Imposition of civil fines

VII. Agenda Item #7 – 10:45 a.m. DEA Update (Sam Curtis)

VIII. Agenda Item #8 – 11:15 a.m. Public Comment #1

IX. Agenda Item #9 – 11:30 a.m. Lunch

X. Agenda Item #10 – 12:00 p.m. Board Business (Chair Holt)

A. Disciplinary matrix

1. Review example
2. Review precedence

B. Application Review

C. Review Lost/Stolen Rx

D. Strategic Plan

1. Review/approve 2021
2. Draft 2022

E. Annual Report

1. 2020
2. 2021 (due June 30)

F. Board of Nursing letter update (12 AAC 44.440(c)(2))

G. Correspondence

1. AKPhA – White bagging
2. FDA – Vaccine safety
3. NABP – Model Act review
4. NABP – 503B Survey
5. NABP – Request for information to VT

H. Board seat nominations

XI. Agenda Item #11 – 1:30 p.m. Work Groups/Subcommittee Updates (Chair Holt)

A. COVID-19 board chairs

B. Controlled Substances Advisory Subcommittee (CSAC)

C. Compounding subcommittee

D. PDMP board chairs

XII. Agenda Item #12 – 2:00 p.m. Industry/Profession Updates

A. AKPhA (Molly Gray/Ashley Schaber)

B. DHSS (Coleman Cutchins/Erin Narus)

XIII. Agenda Item #13 – 2:30 p.m. Division/Budget Update (Melissa Dumas)

XIV. Agenda Item #14 – 3:30 p.m. Administrative Business (Laura Carrillo)

A. License statistics

1. Individual & facility licenses
2. Emergency permits & courtesy licenses
    a. Urgent situation end date

B. Upcoming travel/conferences/workshops

C. Task list review

XV. Agenda Item #15 – 4:00 p.m. Public comment #2

XVI. Agenda Item #16 – 4:15 p.m. Recess until May 21 at 9:00 a.m.

Links

Board of Pharmacy Homepage: pharmacy.alaska.gov

Prescription Drug Monitoring Program State page: pdmp.alaska.gov

ETHICS

CONFIDENTIAL

ETHICS SUPERVISOR DETERMINATION FORM

(Board or Commission Member)

Board or Commission: _____

Member Disclosing Potential Ethics Violation: _____

I have determined that the situation described on the attached ethics disclosure form

- ☐ does or would violate AS 39.52.110 - .190. Identify applicable statute below.
- ☐ does not or would not violate AS 39.52.110 - .190.

_____
Signature of Designated Ethics Supervisor (Chair)

_____
Printed Name of Designated Ethics Supervisor

Date: _____

COMMENTS (Please attach a separate sheet for additional space):

Note: Disclosure Form must be attached. Under AS 39.52.220, if the chair or a majority of the board or commission, not including the disclosing member, determines that a violation of AS 39.52.110-39.52.190 will exist if the member participates, the member shall refrain from voting, deliberating, or participating in the matter. A member will not be liable under the Ethics Act for action in accordance with such a determination so long as the member has fully disclosed all facts reasonably necessary to the determination and the attorney general has not advised the member, chair, or board or commission that the action is a violation. Forward disclosures with determinations to the State Ethics Attorney as part of your quarterly report. Quarterly reports are submitted to Litigation Assistant, Opinions, Appeals & Ethics, Department of Law, 1031 W. 4th Avenue, Suite 200, Anchorage, AK 99501.

Revised 2012

WHO IS MY DESIGNATED ETHICS SUPERVISOR?

Every state public officer, employee or board or commission member, has a designated ethics supervisor.

Executive Agencies

The ethics supervisor for each agency is the Commissioner or a senior manager to whom the Commissioner has delegated the function. The current ethics supervisor for each agency is listed below. The ethics supervisor for a Commissioner is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor.

Boards and Commissions

The Chair of each board and commission serves as the ethics supervisor for the other members and any executive director. The ethics supervisor for the Chair is Shawn Henderson, Director of Administrative Services in the Office of Governor, by delegation from the Governor. If a board or commission employs staff, the executive director serves as the ethics supervisor for these employees.

Public Corporations

The Chair of the board serves as the ethics supervisor for the other members of the board and any executive director. The executive director is the ethics supervisor for employees of the corporation.

Office of the Governor

The ethics supervisor for the Governor and Lieutenant Governor is the Attorney General. By delegation from the Governor, the ethics supervisor for the staff of the offices of the Governor and Lieutenant Governor is Shawn Henderson, Director of Administrative Services.

University of Alaska

By delegation of the University President, the ethics supervisor for university employees is Associate General Counsel Andy Harrington.

EXECUTIVE BRANCH AGENCIES

Administration: Dave Donley, Deputy Commissioner

Commerce, Community & Economic Development: Amy Demboski, Assistant Commissioner

Corrections: April Wilkerson, Administrative Services Director

Education & Early Development: Bobi Jo Grimes, HR Consultant III

Environmental Conservation: Theresa Zimmerman, Human Resources Manager

Fish & Game: Samantha Gatton, Acting Admin Services Director

Health & Social Services: Kimberley King, Human Resource Manager

Labor & Workforce Development: Cathy Muñoz, Deputy Commissioner

Law: Maria Bahr, Assistant Attorney General

Military & Veterans Affairs: Stanley A. Wright, Special Assistant to the Commissioner

Natural Resources: Peter Caltagirone, Special Assistant

Public Safety: Kelly Howell, Special Assistant to the Commissioner

Revenue: Brad Ewing, Administrative Services Director

Transportation & Public Facilities:

- Facility Services: John Binder, Deputy Commissioner
- Aviation: John Binder, Deputy Commissioner
- Central Region: Wolfgang Junge, Regional Director
- Northern Region: Rob Carpenter, Regional Director
- Southcoast Region: Lance Mearig, Regional Director
- Alaska Marine Highway System: Rob Carpenter, Deputy Commissioner
- Headquarters: Rob Carpenter, Deputy Commissioner
    - Administrative Services Division
    - Division of Program Development
    - Information Systems and Services Division
    - Statewide Design and Engineering Services Division

Updated June 2020

ETHICS INFORMATION FOR MEMBERS OF BOARDS & COMMISSIONS (AS 39.52)

Introduction

This is an introduction to AS 39.52, the *Alaska Executive Branch Ethics Act*. This guide is not a substitute for reading the law and its regulations. State board and commission members who have further questions should contact their board chair or staff.

The Ethics Act applies to all current and former executive branch public employees and *members of statutorily created boards and commissions*.

Scope of Ethics Act (AS 39.52.110)

Service on a state board or commission is a public trust. The Ethics Act prohibits substantial and material conflicts of interest. Further, board or commission members, and their immediate family, may not improperly benefit, financially or personally, from their actions as board or commission members. The Act does not, however, discourage independent pursuits, and it recognizes that minor and inconsequential conflicts of interest are unavoidable.

Misuse of Official Position (AS 39.52.120)

Members of boards or commissions may not use their positions for personal gain or to give an unwarranted benefit or treatment to any person. For example, board members may not:

- use their official positions to secure employment or contracts;
- accept compensation from anyone other than the State for performing official duties;
- use State time, equipment, property or facilities for their own personal or financial benefit or for partisan political purposes;
- take or withhold official action on a matter in which they have a personal or financial interest; or
- coerce subordinates for their personal or financial benefit.
- attempt to influence outcome of an administrative hearing by privately contacting the hearing officer.


Terry knew that a proposal that was before the board would harm Terry's business competitor. Instead of publicly disclosing the matter and requesting recusal, Terry voted on the proposal.


Board member Mick has board staff employee Bob type an article for him that Mick hopes to sell to an Alaskan magazine. Bob types the article on State time.

Improper Gifts (AS 39.52.130)

A board member may not solicit or accept gifts if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. "Gifts" include money, items of value, services, loans, travel, entertainment, hospitality, and employment. All gifts from registered lobbyists are presumed to be improper, unless the giver is immediate family of the person receiving the gift.

A gift worth more than $150 to a board member or the board member's immediate family must be reported within 30 days if:

- the board member can take official action that can affect the giver, or
- the gift is given to the board member because he or she is on a state board.

The receipt of a gift worth less than $150 may be prohibited if a person could reasonably infer from the circumstances that the gift is intended to influence the board member's action or judgment. Receipt of such a gift should be disclosed.

Any gift received from another government, regardless of value, must be reported; the board member will be advised as to the disposition of this gift.

A form for reporting gifts is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.

This restriction on gifts does not apply to lawful campaign contributions.


The commission is reviewing Roy's proposal for an expansion of his business. Roy invites all the board members out to dinner at an expensive restaurant. He says it will be okay, since he isn't excluding any of the members.


Jody receives a holiday gift every year from Sam. Jody was recently appointed to a state board, but Sam has no business that is before the board. Jody may accept the gift.

Improper Use or Disclosure of Information (AS 39.52.140)

No former or current member of a board may use or disclose any information acquired from participation on the board if that use or disclosure could result in a financial or personal benefit to the board member (or immediate family), unless that information has already been disseminated to the public. Board members are also prohibited from disclosing confidential information, unless authorized to do so.

 Sheila has been on the board for several years. She feels she has learned a great deal of general information about how to have a successful business venture. So she sets up her own business and does well.

 Delores has always advised and assisted the other doctors in her clinic on their continuing education requirements. After Delores is appointed to the medical board, she discloses this role to the board and continues to advise the doctors in her clinic.

 Jim reviews a confidential investigation report in a licensing matter. He discusses the practitioner's violation with a colleague who is not a board member.

Improper Influence in State Grants, Contracts, Leases or Loans (AS 39.52.150)

A board member, or immediate family, may not apply for, or have an interest in a State grant, contract, lease, or loan, if the board awards or takes action to administer the State grant, contract, lease, or loan.

A board member (or immediate family) may apply for or be a party to a *competitively solicited* State grant, contract or lease, if the board as a body does not award or administer the grant, contract, or lease and so long as the board member does not take official action regarding the grant, contract, or lease.

A board member (or immediate family) may apply for and receive a State loan that is generally available to the public and has fixed eligibility standards, so long as the board member does not take (or withhold) official action affecting the loan's award or administration.

Board members must report to the board chair any personal or financial interest (or that of immediate family) in a State grant, contract, lease or loan that is awarded or administered by the agency the board member serves. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff.*

 John sits on a board that awards state grants. John hasn't seen his daughter for nearly ten years so he figures that it doesn't matter when her grant application comes up before the board.

 The board wants to contract out for an analysis of the board's decisions over the last ten years. Board member Kim would like the contract since she has been on the board for ten years and feels she could do a good job.

Improper Representation (AS 39.52.160)

A board or commission member may not represent, advise, or assist a person in matters pending before the board or commission for compensation A nonsalaried board or commission member may represent, advise, or assist in matters in which the member has an interest that is regulated by the member's own board or commission, if the member acts in accordance with AS 39.52.220 by disclosing the involvement in writing and on the public record, and refraining from all participation and voting on the matter. This section does not allow a board member to engage in any conduct that would violate a different section of the Ethics Act.

 Susan sits on the licensing board for her own profession. She will represent herself and her business partner in a licensing matter. She discloses this situation to the board and refrains from participation in the board's discussions and determinations regarding the matter.

Restriction on Employment After Leaving State Service (AS 39.52.180)

For two years after leaving a board, a former board member may not provide advice or work for compensation on any matter in which the former member personally and substantially participated while serving on the board. This prohibition applies to cases, proceedings, applications, contracts, legislative bills, regulations, and similar matters. This section does not prohibit a State agency from contracting directly with a former board member.

With the approval of the Attorney General, the board chair may waive the above prohibition if a determination is made that the public interest is not jeopardized.

Former members of the governing boards of public corporations and former members of boards and commissions that have regulation-adoption authority, except those covered by the centralized licensing provisions of AS 08.01, may not lobby for pay for one year.

 The board has arranged for an extensive study of the effects of the Department's programs. Andy, a board member, did most of the liaison work with the contractor selected by the board, including some negotiations about the scope of the study. Andy quits the board and goes to work for the contractor, working on the study of the effects of the Department's programs.

 Andy takes the job, but specifies that he will have to work on another project.

Aiding a Violation Prohibited (AS 39.52.190)

Aiding another public officer to violate the Ethics Act is prohibited.

Agency Policies (AS 39.52.920)

Subject to the Attorney General's review, a board may adopt additional written policies further limiting personal or financial interests of board members.

Disclosure Procedures

DECLARATION OF POTENTIAL VIOLATIONS BY MEMBERS OF BOARDS OR COMMISSIONS (AS 39.52.220)

A board member whose interests or activities could result in a violation of the Ethics Act if the member participates in board action must disclose the matter on the public record and in writing to the board chair who determines whether a violation exists. *A form for this purpose is available at www.law.alaska.gov/doclibrary/ethics or from the board or commission staff*. If another board member objects to the chair's ruling or if the chair discloses a potential conflict, the board members at the meeting (excluding the involved member) vote on the matter. If the chair or the board determines a violation will occur, the member must refrain from deliberating, voting, or participating in the matter. For more information, see *Ethics Act Procedures for Boards and Commissions* available at the above noted web site.

When determining whether a board member's involvement in a matter may violate the Ethics Act, either the chair or the board or commission itself may request guidance from the Attorney General.

ATTORNEY GENERAL'S ADVICE (AS 39.52.240-250)

A board chair or a board itself may request a written advisory opinion from the Attorney General interpreting the Ethics Act. A former board member may also request a written advice from the Attorney General. These opinions are confidential. Versions of opinions without identifying information may be made available to the public.

REPORTS BY THIRD PARTIES (AS 39.52.230)

A third party may report a suspected violation of the Ethics Act by a board member in writing and under oath to the chair of a board or commission. The chair will give a copy to the board member and to the Attorney General and review the report to determine whether a violation may or does exist. If the chair determines a violation exists, the board member will be asked to refrain from deliberating, voting, or participating in the matter.

Complaints, Hearings, and Enforcement

COMPLAINTS (AS 39.52.310-330)

Any person may file a complaint with the Attorney General about the conduct of a current or former board member. Complaints must be written and signed under oath. The Attorney General may also initiate complaints based on information provided by a board. A copy of the complaint will be sent to the board member who is the subject of the complaint and to the Personnel Board.

All complaints are reviewed by the Attorney General. If the Attorney General determines that the complaint does not warrant investigation, the complainant and the board member will be notified of

the dismissal. The Attorney General may refer a complaint to the board member's chair for resolution.

After investigation, the Attorney General may dismiss a complaint for lack of probable cause to believe a violation occurred or recommend corrective action. The complainant and board member will be promptly notified of this decision.

Alternatively, if probable cause exists, the Attorney General may initiate a formal proceeding by serving the board or commission member with an accusation alleging a violation of the Ethics Act. Complaints or accusations may also be resolved by settlement with the subject.

CONFIDENTIALITY (AS 39.52.340)

Complaints and investigations prior to formal proceedings are confidential. If the Attorney General finds evidence of probable criminal activity, the appropriate law enforcement agency shall be notified.

HEARINGS (AS 39.52.350-360)

An accusation by the Attorney General of an alleged violation may result in a hearing. An administrative law judge from the state's Office of Administrative Hearings serves as hearing officer and determines the time, place and other matters. The parties to the proceeding are the Attorney General, acting as prosecutor, and the accused public officer, who may be represented by an attorney. Within 30 days after the hearing, the hearing officer files a report with the Personnel Board and provides a copy to the parties.

PERSONNEL BOARD ACTION (AS 39.52.370)

The Personnel Board reviews the hearing officer's report and is responsible for determining whether a violation occurred and for imposing penalties. An appeal may be filed by the board member in the Superior Court.

PENALTIES (AS 39.52.410-460)

When the Personnel Board determines a board member has violated the Ethics Act, it will order the member to refrain from voting, deliberating, or participating in the matter. The Personnel Board may also order restitution and may recommend that the board member be removed from the board or commission. If a recommendation of removal is made, the appointing authority will immediately remove the member.

If the Personnel Board finds that a former board member violated the Ethics Act, it will issue a public statement about the case and will ask the Attorney General to pursue appropriate additional legal remedies.

State grants, contracts, and leases awarded in violation of the Ethics Act are voidable. Loans given in violation of the Ethics Act may be made immediately payable.

Fees, gifts, or compensation received in violation of the Ethics Act may be recovered by the Attorney General.

The Personnel Board may impose a fine of up to $5,000 for each violation of the Ethics Act. In addition, a board member may be required to pay up to twice the financial benefit received in violation of the Ethics Act.

Criminal penalties are in addition to the civil penalties listed above.

DEFINITIONS (AS 39.52.960)

Please keep the following definitions in mind:

Benefit - anything that is to a person's advantage regardless financial interest or from which a person hopes to gain in any way.

Board or Commission - a board, commission, authority, or board of directors of a public or quasi-public corporation, established by statute in the executive branch, including the Alaska Railroad Corporation.

Designated Ethics Supervisor - the chair or acting chair of the board or commission for all board or commission members and for executive directors; for staff members, the executive director is the designated ethics supervisor.

Financial Interest - any property, ownership, management, professional, or private interest from which a board or commission member or the board or commission member's immediate family receives or expects to receive a financial benefit. Holding a position in a business, such as officer, director, partner, or employee, also creates a financial interest in a business.

Immediate Family - spouse; another person cohabiting with the person in a conjugal relationship that is not a legal marriage; a child, including a stepchild and an adoptive child; a parent, sibling, grandparent, aunt, or uncle of the person; and a parent or sibling of the person's spouse.

Official Action - advice, participation, or assistance, including, for example, a recommendation, decision, approval, disapproval, vote, or other similar action, including inaction, by a public officer.

Personal Interest - the interest or involvement of a board or commission member (or immediate family) in any organization or political party from which a person or organization receives a benefit.

For further information and disclosure forms, visit our Executive Branch Ethics web site or please contact:

State Ethics Attorney
Alaska Department of Law
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
(907) 269-5100
attorney.general@alaska.gov

Revised 9/2013

EXECUTIVE BRANCH ETHICS ACT

Responsibilities of Designated Ethics Supervisors for Boards and Commissions

Boards and commissions subject to the Ethics Act have designated ethics supervisors. The chair serves as the designated ethics supervisor for board or commission members and the executive director. The executive director is the designated ethics supervisor for staff. The designated ethics supervisor for a chair is the governor, who has delegated this responsibility to Guy Bell, Administrative Director of the Office of the Governor.

Designated ethics supervisors should refer to the **2019 Designated Ethics Supervisors Handbook** (503KB PDF), available from the state ethics attorney, regarding their responsibilities under the Ethics Act. Briefly, as designated ethics supervisor, you must --

1. Ensure that members and employees are provided copies of the guides, Ethics Information for Members of Boards and Commissions and Ethics Act Procedures for Boards and Commissions -- and keep a supply of disclosure forms.
    1. These guides, other educational materials, disclosure forms, statutes and regulations are available for review and copying on the Department of Law ethics web site. If access to this page is not available, please contact the Attorney General's office at 269-5275.
2. Review all disclosures, investigate potential ethics violations, make determinations regarding conduct, and take action.
3. Keep member or employee disclosure statements (of potential violations, receipt of gifts, and interests in grants/contracts/leases/loans) on file in your office. Disclosure of a gift received from another government must be forwarded to the Office of the Governor.
4. Submit an ethics report to the Department of Law in April, July, October and January for the preceding quarter. You will receive a reminder. There is a sample report on the ethics web page.
    1. Mail, email or fax to Jennifer L. Williams, Paralegal, Department of Law, Opinions, Appeals & Ethics Section, 1031 W. 4th Avenue, Suite 200, Anchorage, AK, 99501, ethicsreporting@alaska.gov, fax no. 907-258-4978.

You may request ethics advice from your agency's Assistant Attorney General or from the State Ethics Attorney, Maria Bahr, at 269-5285 or maria.bahr@alaska.gov. Please direct questions about reporting procedures to Jennifer L. Williams at 269-5275 or jennifer.williams1@alaska.gov.

6/19

MINUTES

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE EMERGENCY MEETING

February 18 - 19, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on February 18 - 19, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:02 a.m.**

The day 1, **February 18, 2021** videoconference was called to order by Chair, Rich Holt at 9:02 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member (joined at 1:05 p.m.)
Sharon Long, Public Member
Justin Ruffridge, #PHAP1787

Division staff present:

Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Heather Noe, Occupational Licensing Examiner
Bethany Carlile, Occupational Licensing Examiner
Sonia Lipker, Lead Investigator
Michael Bowles, Investigator III
Sharon Walsh, Deputy Director
Melissa Dumas, Administrative Officer

Members from the public present/registered:

Pauline Henriques-Perry, Division of Legislative Audit
Sheila Sinclair, Trilogy Medwaste
Lauren Paul, CVS Health
Rob Geddes, Albertsons Companies
Lorri Walmsley, Walgreens
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Tribal Health Consortium
Caren Robinson, AkPHA
Anne Harthman, Broadway Apothecary
Lis Houchen, NACDS
Jennifer Adams, Idaho State University College of Pharmacy
Rich Palombo, Express Scripts/Cigna
Christy Grennon, ABC
Brenda Walker, VA
Jessica Adams, TelePharm
Molly Gray, Alaska Pharmacists Association
James J Henderson, Division of Legislative Audit
Emily Haugh, Amazon Pharmacy
Gretchen Glaspy, Alaska Pharmacy Association/Bartlett Regional Hospital
Erin Narus, SOA

Agenda Item 2 **Review/Approve Agenda** **Time: 9:05 a.m.**

Chair Holt went through the agenda for day 1. Ms. Carrillo commented two additional pieces of correspondence were added to the OnBoard packet and additional legislative documents were added to the budget report/division update for Agenda Item #13.

On a motion duly made by Lana Bell to approve the meeting agenda, seconded by Justin Ruffridge, and approved unanimously, it was:

RESOLVED to accept the February 18, 2021 meeting agenda as written.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion.

Agenda Item 3 **Ethics** **Time: 9:09 a.m.**

For transparency, Chair Holt reminded the board and the public that he currently participates in the biweekly COVID-19 board chairs meeting as well as the biweekly PDMP board chairs meeting.

Agenda Item 4 **Review/Approve Meeting Minutes** **Time: 9:11 a.m.**

The board reviewed the November 5 – 6 and December 3 – 4, 2020 draft meeting minutes.

On a motion duly made by Sharon Long to approve the meeting agenda, seconded by Lana Bell, and approved unanimously, it was:

> **RESOLVED to approve the November 5 – 6, 2020 and December 3-4, 2020 meeting minutes as written.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 1
Ms. Carrillo will send the minutes to Chair Holt for signature and request they be published to the board's meeting page.

Agenda Item 5 **Public Comment** **Time: 9:15 a.m.**

There were no public comments.

Agenda Item 6 **PDMP Update** **Time: 9:20 a.m.**

Board Report
Ms. Sherrell provided the board the update that Appriss Health was awarded the contract for the PDMP to continue providing the platform, AWARxE. Ms. Sherrell noted several enhancements are in limbo until the contract can be finalized and executed, but that the goal date is April 2021.

The PDMP also received the Notice of Award for the Bureau of Justice Assistance (BJA) grant with funding through September 2023. The board also and had its Awareness & Feedback Questionnaire from February/March 2020 evaluated. There were 110 pharmacists who participated in the questionnaire. Ms. Sherrell informed the board the 2021 questionnaire would be launched in the spring following the end of program renewals. Ms. Sherrell also presented the data on registration, reviewing, and reporting.

Ms. Sherrell reviewed licensee compliance data and informed the board a letter was sent to 94 pharmacies informing them of missing or delinquent data submissions. Responses have positive and Ms. Sherrell is assisting pharmacies submit or resubmit data. Dr. Holm inquired whether there was a delinquent threshold date that triggered the letter, to which Ms. Sherrell indicated was 1. Ms. Sherrell also indicated some pharmacies weren't actually dispensing or distributing controlled substances and one hadn't switched their software over. Dr. Holm commented he's not able to manually correct delinquent dates, and Ms. Sherrell explained the delinquent date is a historical mark. Several reports have to be pulled to gain a more accurate picture of the delinquency data. Ms. Carrillo explained we could pull a dispensary activity report, which would show data submitted, even if done retroactively.

Ms. Sherrell reviewed recommendations to prescribing boards and acknowledged a lot of education is needed to explain to providers what it means to dispenses and encourage the use of delegates. Prescribing boards have also been asked to come up with plans to address delinquent reporting.

Ms. Sherrell then reviewed the prescriber report card aggregate data, which describes the # of prescribers prescribing at least once, # who reviewed zero patients, # of providers prescribing over 90MME, and # issuing dangerous combination therapies. Chair Holt inquired what the MED board's dangerous combo of benzos, opioids, and carisoprodol had gone down from 47 to 21. NUR also decreased. Chair Holt explained that the benzo, opioid, and carisoprodol is considered the holy trinity by the DEA, and they are investigated for dispensing this combination; pharmacists are being arrested for dispensing them. Chair Holt presented relevant articles to the PDMP Board Chairs meeting, and Dr. Wein commented he couldn't see any medically justifiable reason for dispensing that combination. Chair Holt recalled an inquiry made to AAG Weigand around establishing regulations for dispensing off-label uses hydroxycholorquine, alluding to the need for drafting regulations. Similarly, an inquiry was made around not dispensing dangerous combinations since pharmacists are getting arrested for dispensing the holy trinity.

Ms. Sherrell returned to the questionnaire: Over half of pharmacists (55%) reviewed prior to dispensing or at least once a day (29%). The majority of pharmacists (85%) lacked confidence that the prescriber was checking. Ms. Sherrell indicated she was surprised at the high number of pharmacists (79%) who had denied a prescription. Almost half of the pharmacist indicated there was a barrier, but those who said there was cited a lack of time and not due to a lack of education or understanding. This is where use of a delegate can be beneficial to reviewing patients when there is limited time.

Legislative Report (2020)

Ms. Carrillo referred to the board's previously PDMP legislative report, which is typically submitted in February or March. As an overview, Ms. Carrillo explained there are certain metrics that must be included in the report, including how use of the PDMP contributed to the reduction of inappropriate prescriptions being issued. Ms. Carrillo informed the board this year's report will highlight some of the challenges but also the level of outreach provided to assist licensees come into compliance and better understand the program. Chair Holt reiterated the board's education and outreach has gone beyond what may be sufficient and thanked Ms. Sherrell and Ms. Carrillo for their continued work and participation at the other boards' meetings.

Disciplinary Matrix

Ms. Carrillo gave a recap of the board's disciplinary matrix for reporting and the September, 2020 letter setting the basis for quarterly compliance reviews beginning January 1, 2021. Ms. Carrillo prompted the board to discuss what continuous delinquency means, is it # of days, # of prescriptions, etc. Ms. Carrillo also added the matrix would establish a guide for staff to know when to refer a matter to the investigative unit.

Dr. Ruffridge's approach would be to target those pharmacies not reporting at all and not responding to delinquent notices from the Board. He acknowledged there are multiple levels where a report submission could go wrong, but that a meaningful effort to respond to the letter demonstrates a desire to change. Dr. Ruffridge added there's not a way currently to notify the provider when there is a missed reporting day, and Ms. Sherrell indicated Appriss tested this in another state, which resulted in pharmacies receiving false alerts. Staff is working on implementing this in Alaska after lessons learned from other states.

Sharon Long inquired about what level of delinquency triggers a reprimand that costs $5,000, emphasizing the need to allow human discretion and the ability for the board to assess on an individual basis. Ms. Bell stated education is needed to get providers to understand, but that it has been 4 years since mandatory use. Chair Holt inquired whether the board wanted to refer licensees who don't notify us when they are not dispensing or distributing. Ms. Carrillo commented it's not currently in regulations, so questioned whether we could refer something to Investigations of the letter doesn't have the force of law. Ms. Bell asked whether pharmacies have the opportunity to report what their dispensing or distributing status, to which Ms. Carrillo confirmed. Dr. Holm acknowledged this is mandatory and expressed support of being more stern.

Chair Holt posed to the board that when the one reviewing board member looks at these cases after the next scheduled review in April, what is the board member going to go off of to determine what their recommendation is going to be? Dr. Ruffridge stated it would fall under daily reporting reprimand. Dr. Holm reviews these carefully and doesn't take potential non-compliance lightly. Investigator, Michael Bowles, indicated that during the reviewing process, the reviewing board member can recommend suspension. This then comes back to the investigator who creates an accusation, which goes to the AAG, then goes back to the board with the recommended suspension.

The board expressed most concern over pharmacies that haven't reported at all versus # of days missing, # of errors, or # of prescriptions. Ms. Bell commented that if pharmacies are receiving the letters but not responding to explain why they're not reporting is a problem and they should be held accountable. Dr. Holm agreed. The board would return to discussing other subsets of delinquent reporters at a later date.

On a motion duly made by Justin Ruffridge, seconded by Leif Holm, and approved unanimously, that during the April quarterly compliance audit, those entities that are non-reporting and have not made a good faith effort to discuss with the PDMP manager their issues with reporting, should be referred to investigations. Potential actions will be guided by the board's disciplinary matrix, it was:

> **RESOLVED to accept the procedure for the April 2021 compliance review audit to refer pharmacies not reporting and not responding to delinquent notices.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion.

On a motion duly made by Justin Ruffridge to amend the disciplinary matrix to define delinquent reporting specific to continued submission delinquencies as receiving no reports and no response to the Board of Pharmacy, seconded by Lana Bello, and approved unanimously, it was:

> **RESOLVED to approve the amend PDMP disciplinary matrix to add to the proposed sanction the operational definition of continued delinquency as non-reporters and non-responders to delinquent notices.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x

James Henderson		x
Sharon Long	x	

The motion passed with no further discussion.

Board of Pharmacy - Prescription Drug Monitoring Program
Approved Disciplinary Matrix as of February 18, 2021

Complaint	Proposed Sanctions
Registration (AS 17.30.200(e)(n), 12 AAC 52.855): • No registration • Delayed registration – not registered within 30 days	(Notice sent on July 7, 2020 via board letter to all pharmacists with Alaska addresses). $250 civil fine beginning on October 1, 2020 (or after 30 days of initial licensure or after beginning to dispense schedule II, III, or IV federally controlled substances) and an additional $25 per day until registration is completed.
Delinquent Reporting (AS 17.30.200(b)(e), 12 AAC 52.865): • Daily reporting (12 AAC 52.865)(b))	(Warning issued September 16, 2020 via board letter to all licensees). As of January 1, 2021, quarterly compliance audits will track delinquent submissions of data to the PDMP. • First reprimand: $5,000 civil fine for continued submission delinquencies • Continued submission delinquencies may result in license suspension. A "continued submission delinquency" means a pharmacy that has not reported or responded to notices by the Board.
Unauthorized Access (AS 17.30.200(d)(4))	TBD

TASK 2
Ms. Carrillo will forward the revised disciplinary matrix to the investigative unit for their records.

Agenda Item 7 Board Business Time: 11:15 a.m.

Hearing nothing further on PDMP updates, Chair Holt moved to discussing board business.

Reports of Theft/Loss
The board reviewed reports from Bartlett Regional Hospital and Walgreens.

Board Website FAQs
Ms. Carrillo directed the board to the FAQs page, noting it needed to be revised for accuracy and whether any items have become obsolete. Dr. Ruffridge commented that upon initial review, there were several FAQs that were no longer applicable. Chair Holt commented the board's position on some of the FAQs may have also changed. Ms. Carrillo reminded the board of their new position statement page and that some FAQs could be turned into position statements. The board discussed delegating a subcommittee to review this page, however, Dr. Ruffridge volunteered.

TASK 3
Dr. Ruffridge will review the website FAQs for accuracy and applicability and recommend at the board's next meeting what FAQs need to be added, updated, removed, or turned into position statements.

Update on Letter to Board of Nursing

Ms. Carrillo pointed to the board's letter sent to the Board of Nursing regarding 12 AAC 44.440(c)(2) requiring certain details be present on the label for it to be dispensed by a pharmacy. Chair Holt inquired that if a prescription is presented to a pharmacy that doesn't contain the credentials, "APRN" after the signature and doesn't contain their professional license number, is it considered a valid prescription? Chair Holt also considered whether the responsibility to obtain missing information falls to pharmacists. Ms. Long's opinion is the board shouldn't go in the direction of being an enforcer for non-compliance issues with the nurse practitioner, adding they can notify them of the missing information but let them and their boards deal with that infraction. Ms. Long also stated the pharmacist could take the time to file a complaint with the appropriate unit but discouraged policing this matter.

Ms. Carrillo inquired whether there were repercussions on the pharmacist end if these medications were dispensed. Chair Holt recalled a situation in which a pharmacy was audited and a third-party company found the medications weren't dispensed according to state law, adding the pharmacy was attempting to recoup the cost back. Ms. Long expressed that may be one example, but we don't always know the ultimate outcome of the liability.

Correspondence: Nancy Kavan

The board reviewed correspondence from pharmacist, Nancy Kavan. Dr. Kavan inquired about providing input on the jurisprudence test. Upon review, it was unclear whether she was referring to the MPJE or the jurisprudence questionnaire, the latter of which has been removed from renewal applications.

TASK 4

Ms. Carrillo will follow up with Nancy Kavan to find out if she was referring to the jurisprudence questionnaire or the MPJE.

Correspondence: NABP

The 117th Annual Meeting will be held virtually on May 13 and 14, 2021. Dr. Ruffridge expressed an interest in attending. Ms. Carrillo also indicated her intent to participate. Ms. Carrillo recalled from participating in 2018 the major topics being nationally certified technicians, which the board has since adopted regulations for, and pharmacist prescriptive authority, which is on the board's agenda for day 2. Ms. Carrillo then informed the board the most recent version of the pharmacy law is available.

The NABP also began issuing exam scores for the MPJE and NAPLEX with a pass/fail instead of representing the score with a percentage. Ms. Carrillo stated it doesn't affect the board's current pass/fail regulations as the NABP's pass threshold is at 75%, which aligns with the board's requirements. The board then reviewed the MPJE item workshop correspondence, which will be held remotely from March 1 – 26. The purpose of the workshop is to write law questions. Chair Holt described the process of participating: the NABP emails the participant a secure file around categories of law, e.g.: hazardous waste, licensing, and professional practice; a list will be provided

showing how many questions Alaska has and categories each question into its corresponding category topic; and a list of questions that were previously developed but are still in the testing phase in review by a committee. Chair Holt also clarified that the workshop isn't the time to remove questions, but it's possible to still assess for applicability. All questions go through a statistical model to determine whether they are "good" questions.

Ms. Carrillo inquired whether the NABP provides participants with the exam pass rate. Chair Holt's recollection from a few years ago was that it was around 80%. Dr. Holm asked how many questions participants are expected to write, to which Chair Holt indicated was about 20-30. Dr. Holm expressed an interest in participating but wanted to know if the writing could be split up between more than one participant. Chair Holt asked Ms. Carrillo to inquiry about how questions could be split between multiple participants, adding he would also be interested in participating.

TASK 5
Ms. Carrillo will contact the NABP to register herself and Dr. Ruffridge for the 117th Annual Meeting.

TASK 6
Ms. Carrillo will contact the NABP to inquire if exam writing can be split between multiple participants and what that process might entail.

Ms. Long circled back to the correspondence from an applicant who had submitted a letter to withdraw. Due to this specific matter being discussed in executive session, the board expressed it would be appropriate to again go into executive session, sometime after lunch.

Leif Holm left the room at 11:46 a.m.

Correspondence: Jessica Adams
The board reviewed correspondence from Jessica Adams with TelePharm and Ms. Carrillo noted the board had previously discussed remote pharmacy regulations.

Strategic Plan
Ms. Carrillo pulled up the board's 2020 strategic plan and inquired whether the board had anything to add to it for 2021. Ms. Carrillo stated she would work on the 2021 strategic plan and present it to the board during their May meeting. If approved, Ms. Carrillo will post it to the website.

TASK 7
Ms. Carrillo will work on the board's 2021 strategic plan for review and discussion during the May meeting.

Chair Holt called for lunch at 11:58 a.m.

Off record at 11:58 a.m.

On record at 1:04 p.m.

Agenda Item 8 Lunch **Time: 11:58 a.m.**

Upon return from lunch, Ms. Carrillo performed a roll call.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member
Sharon Long, Public Member
Justin Ruffridge, #PHAP1787

The board recalled their intent from before lunch to enter executive session to discuss an applicant matter.

On a motion duly made by Richard Holt in accordance with AS 44.62.310(c)(2), the board unanimously moved to enter executive session for the purpose of discussing subjects that tend to prejudice the reputation and character of any person, provided the person may request a public discussion.

RESOLVED to enter into executive session in accordance with AS 44.62.310(c)(2).

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion.

Off record for executive session at 1:07 p.m.
On record from executive session at 1:37 p.m.

In the interest of the time, Chair Holt moved to Agenda Item #10, after which time the board would address Agenda Item #9 for Work Group/Subcommittee Updates.

Agenda Item 10 Industry/Profession Updates Time: 1:39 p.m.

AKPhA (Molly Gray)

Ms. Gray provided an update on its annual meeting on February 14; the AKPhA had 10 sponsors and were able to provide 16 hours of continuing education credit, with an additional 5 hours of CE available. Ms. Gray also expressed thanks to Ms. Sherrell and Dr. Ruffridge for their update on behalf of the Board of Pharmacy and PDMP. Ms. Gray then recalled the awards presented to outstanding pharmacists, including Bowl of Hygia Award, which was awarded to Chair, Rich Holt. Other items from the NABP update include an immunization training program and a virtual Zoom fly-in for connecting with legislators.

Agenda Item 9 Work Group/Subcommittee Updates Time: 1:44 p.m.

COVID Chairs

Dr. Holt informed the board he continues to meet bi-weekly with healthcare boards.

CSAC

Ms. Lindemuth indicated the committee met last Tuesday after not meeting since October. The committee decided to make a recommendation to Governor Dunleavy to schedule Kratom as a IIIA controlled substance. The committee is also continuing to discuss scheduling gabapentin. Ms. Lindemuth clarified that if gabapentin is scheduled as VA, it won't interfere with continuity of care but would be a benefit to the criminal justice system with by providing the ability to prosecute related matters. looking at it is the benefit of the criminal justice system and help prosecutions;

Agenda Item 10 Industry/Profession Updates Time: 1:50 p.m.

The board returned to industry/profession updates as Dr. Narus was on the line to discuss pharmacist enrollment, Medicaid regulations, and the federal retail pharmacy program. Dr. Narus provided that there were 112 pharmacists enrolled and 10 pharmacy professional groups. Over 5,000 vaccine administrations have occurred in assisted living homes and several other hundreds who have been vaccinated by state pharmacy partners in regions were CVS and Walgreens aren't located. Dr. Narus added Alaska has been slightly impacted by the weather that's occurred in the lower 48 in terms of vaccine availability, but we anticipate this smoothing out over the next few weeks. Over the last two weeks, the next tier of populations eligible to receive vaccines has opened up critical care employees 50 years and older and teachers.

Dr. Narus then reviewed the Federal Retail Pharmacy Program for COVID-19, which is a collaboration between the federal government, states and territories, and national pharmacy partners to expand access to vaccinations.

Dr. Narus then reviewed the Medicaid coverage regulations from the Department of Health and Social Services. The regulations include language related to reimbursements and allowing pharmacists to administer vaccines within their scope and without a collaborative practice to be

reimbursed. Language was also amended to be able to provide vaccine products in future disaster emergencies so existing efforts aren't limit just to COVID-19 in the event another health emergency emerges. Dr. Narus also discussed the Vaccine for Children Program; pharmacies must be enrolled in the program in order to be reimbursed for providing vaccines given to a child under 18 and younger.

Dr. Narus then turned to regulations that went into effect in on 02/12/2021 related to Medicaid coverage and payment for pharmacy services during a declared emergency. There is also a provision extending the standard 34-day fill to a 68-day fill to result in enhanced dispensing. The board and discussed reimbursement models and state versus federal vaccine allocations. The standard state allocation hinges on a per capita allocation, which involves taking a big bucket of vaccines and distributing it amongst the state. There is also a separate bucket for federal retail partnerships and other allocations for the IHS, DOD, and VA. The long-term care program uses state allocated vaccines.

Documents Dr. Narus referenced in this update can be found in the public board packet posted to pharmacy.alaska.gov.

Agenda Item 11 **Public Comment 2** **Time: 2:17 p.m.**

There were no public comments.

Agenda Item 9 **Work Group/Subcommittee Updates** **Time: 2:22 p.m.**

The board returned to subcommittee updates.

CSAC (continued)
Ms. Lindemuth clarified that the recommendation to the Governor would be compounds within kratom, including mitragynine. The next CSAC meeting will be from May 11 from 2:30 p.m. to 5:00 p.m. Ms. Carrillo commented that at a recent PDMP Chairs meeting, the possibility of inviting a member from the CSAC to their next meeting on March 2nd. Ms. Lindemuth indicated she would be interested in attending.

TASK 8
Ms. Carrillo will reach out to Ms. Lindemuth about joining the PDMP Chairs Meeting.

Compounding Subcommittee
Dr. Holm informed the board there was nothing new to report other than draft regs that were started a few months ago. Dr. Holm and Dr. Ruffridge will continue working on this.

PDMP Chairs
Chair Holt informed the board the meetings continue to be a place to discuss ongoing matters, assisting other professionals, providing details as to what the Board of Pharmacy has done, and

demonstrating what has been successful for our program. Chair Holt stated overall it is a good discussion group, and reiterated the invitation for Ms. Lindemuth to attend.

AKPhA

Dr. Ruffridge indicated he's still assisting with work on the introduction of the mobilization act. The AKPhA is working with Sen. Revak for drafting that has come back from legal and are waiting on a final draft before it's introduced to the floor. Dr. Ruffridge expressed his excitement to see this go forward based on the discussion from the last meeting.

Agenda Item 12 Investigative Report Time: 2:30 p.m.

Investigator, Michael Bowles joined the board as their newly assigned investigator. Investigator Lipker stated Investigator Jacobs had left the unit and that Mr. Bowles volunteered to assist the Board of Pharmacy. Mr. Bowles introduced himself to the board, stating his background is in healthcare administration. He was previously in the army and is finishing his master's degree in healthcare administration.

Mr. Bowles then presented the investigative report, which included activity from October 27 through February 5, 2021. There are 48 cases open and 13 PDMP cases have since been closed, with an additional 13 matters also closed. Mr. Bowles explained that once their unit receives a formal complaint packet or they find an issue once reviewing the packet, the matter is elevated to an investigation. The complaint stage can be considered an "inquiry" stage.

Chair Holt referred to the historical matters from 02/15/2017 and 06/06/2017. Investigator Bowles indicated these have already been presented to the board, but we are waiting for the respondent. Investigator Lipker added they couldn't discuss specifics with each case; but generally, these matters were initially opened in 2017 and since closed, but because applications were received to renew, the matters were re-opened within the same case #. Ms. Lindemuth pointed to a 2018 complaint, to which Mr. Bowles indicated it had since been elevated to an investigation.

Ms. Lindemuth inquired about the timeframe for closing an investigation. Investigator Bowles indicated the goal is 6 months, adding that if it is a matter arising from an application issue, resolution is typically within that timeframe, but if it's something more complicated, e.g.: from a CMS audit and results come back as there being extreme unprofessional conduct, it can take years. Investigator Lipker stated it can be confusing because "investigation" is actually used sparingly; the unit calls it a complaint for the purpose of communicating that to the licensee, but "investigation" is used towards the end of the matter.

Ms. Carrillo also pointed to the inspection checklist and example letter, which was a task from the previous meeting. Chair Holt asked that all board members review the checklist to review for relevance and for discussion at the next meeting, similar to the FAQs task, so the board can provide input on what should be inspected during an audit.

Task 9
All board members review the checklist and sample letter in preparation for discussion at the next meeting.

Chair Holt called for break at 2:45 p.m.

Off record at 2:45 p.m.
On record at 2:55 p.m.

Agenda Item 13 **Budget Report/Division Update** **Time: 2:56 p.m.**

Deputy Director Walsh joined the board to present its FY21 1st quarter report. The board's ending 1st quarter revenue is at $738.420, which is reflected in the influx of revenue due to renewal. Total expenditures is at $131,957, the bulk of which includes nearly $54,000 in personal services and about $14,000 in investigative expenditures for indicator costs. For indirect expenditures, the placeholder is at $64,000 to internal administrative costs, departmental costs, and statewide costs. The board's cumulative surplus is at $825,693. Deputy Director Walsh then pointed to the FY21 1st and 2nd combined quarter, which reflects a total revenue of $893,427, total expenditures over $302,013, and an ending cumulative surplus of $810,644.

Ms. Long inquired why the board would operate on a surplus over $800,000, to which Administrative Officer, Melissa Dumas, indicated the division is required to maintain a neutral fund with surplus and the cost to run the program. A surplus is not obscene; it's more than 1 year's worth of expenditures, which is what the department usually strives for to account for variable costs that we can't anticipate.

Ms. Dumas, went over the board's PDMP report, which reflects nearly $33,000 in revenue from the user fee. Ms. Dumas indicated there will be adjustments due to incorrect coding, which will result in an increase in revenue once corrected. Expenditures charged to the program include time occupational licensing examiners spend to process registrations. It was also added that two grants were received that will allow the program to charge investigative time.

Moving to the fee analysis, Ms. Dumas indicated the division hasn't proposed a new fee amount for any license category. Ms. Dumas also clarified that when looking at expenditures from personal services, the board will expect to see that increase slightly due to the new occupational licensing examiner. Ms. Carrillo inquired about the fingerprinting fee and when there would be an opportunity to make changes to the centralized fee regulations. Ms. Dumas indicated she would look into that.

The board did not propose to adjust the fees.

Task 10
Ms. Carrillo will follow-up with Ms. Dumas on amending centralized regulations to include fingerprint fees for the Board of Pharmacy.

Deputy Director Walsh then moved to discussing general legislative updates that may affect the division or the board of pharmacy. The board inquired, with regards to the AKPhA modernization bill, what the protocol is for supporting their efforts. Deputy Director Walsh indicated the board should go on the record with what the board supports specifically. If there are any changes, this would be a good opportunity to address that while the members are on record and assembled. Deputy Director Walsh added that the board needs to ensure if they're on record supporting the bill, there shouldn't be any section that, once in a hearing, the board finds they are not in support of.

Ms. Carrillo then addressed SB70, which is the standing order legislation to remove the sunset date for issuing naloxone. Chair Holt inquired how the standing order is being used currently; whether providers are using their existing scope or if it's private citizens. Ms. Carrillo indicated her understanding that it applies to professionals listed in a specific subjection of the law, which includes pharmacists and other healthcare providers. Ms. Carrillo added the source of naloxone kits may be coming from DHSS' grant-funded Project Hope, to which Dr. Ruffridge confirmed.

TASK 11
Ms. Carrillo will reach out to OSMAP for how the standing order is being used and by whom, and where the source of the kids are coming from.

Agenda Item 14 **Administrative Updates** **Time: 3:45 p.m.**

Continuing Education Audit
Ms. Carrillo informed the board that 9 licensees initially appeared to not have complied with the continuing education audit. Upon further review, 3 had complied with their audit, but documentation was not immediately visible due to licensees not adding Alaska to their NABP eProfile. Ms. Carrillo indicated there will need to be clear instruction on next year's renewal application to be sure to add Alaska as a state to avoid being flagged as potentially non-compliant.

Outstanding Information Update
Ms. Carrillo stated there initially appeared to be 202 reports missing from 2017 and 70 reports missing from 2019. Further review revealed some pharmacies had submitted these, but were filed under different document categories, e.g.: report, annual information update, and annual report. Ms. Carrillo stated she would be working to improve tracking by coordinating with staff on how to scan and file these documents using one type of filing category. Ms. Noe is receiving responses to the missing reports and filing them accordingly.

Task Lists

Ms. Carrillo reviewed the task lists from the November and December 2020 meetings. All tasks have been completed, with the two pending regulations tasks set for discussion on day 2.

Task Lists: Definition of "administer" and Negative-Implication Canon

One task included asking DOL to clarify why it is required to state "administer" on the prescription from the *practitioner*, if it is already in the pharmacists' scope under AS 08.80.480(3) to engage in "drug administration." As an example, the board asked that if a patient is COVID-19 positive, can the pharmacist administer immunoglobulin without an order. DOL via AAG Megyn Weigand responded they cannot without an order from the practitioner. The board also asked what was required to be on the order to give pharmacists explicit instruction to administer, to which AAG Weigand indicated "administer" must be clearly stated; pharmacists cannot assume they can administer, for example, if they receive an order for an injectable drug.

AAG Weigand went on to describe the Negative-Implication Canon, which is a rule excluding unspecified items when existing language does specify others. The result is the prohibition against engaging in or authorization certain items if they are not clearly listed, but other items are. An example would be if the board's statutes allowed administering of specific drugs, the drugs not listed would then be prohibited from being administered. The board expressed concern about this rule and requested clarification as to whether there was any leeway, or if defining something truly has an exclusionary effect.

Dr. Ruffridge highlighted that the board's COVID emergency response was successful largely because of defining language around vaccines and emergency medications, but questioned whether this has inadvertently pigeon-holed the board, and restricting them from expanding out in the future, to antipsychotic meds, for example. Ms. Long also expressed concern, believing there must be some wiggle language to allow boards to be more flexible instead of having to list everything under the sun to not fall into this negative implication principle. Ms. Long recalled her time working with the legislature when there were challenges prohibiting designer drugs; if a few isotopes were changed, it wouldn't be prohibited anymore, so it seems there are solutions DOL can help the board with.

TASK 12

Ms. Carrillo will follow up with Deputy Director Walsh to request clarification on the Negative Implication Canon.

Task List: Remote Order Pharmacy Services by Out-of-State Pharmacy

The board then moved to the task relating to remote order entry services performed by out-of-state pharmacies. Ms. Carrillo recalled this involved a specific out-of-state pharmacy that was tied to a pharmacist license application. Dr. Ruffridge clarified the matter related to the ability for non-resident pharmacies to perform remote order entries though the regulation limits that to in-state pharmacies only.

Ms. Carrillo included a response from DOL for which the board asked for clarification around whether an out-of-state pharmacy can provide telepharmacy services without an Alaska pharmacist license. The guidance went on to state there is no prohibition between non-resident pharmacies partnering with in-state pharmacies, but that the central pharmacy and pharmacist employed by the central pharmacy must be Alaska-licensed. Ms. Carrillo interpreted this meaning that out-of-state pharmacies cannot perform remote services since the regulation only applies to central and remote pharmacies in the state, but that the out-of-state pharmacist must be licensed; essentially the pharmacist can be licensed but not perform these duties under the employment of a non-resident pharmacy.

The board requested additional information as to the circumstances surrounding the pharmacist's application status. Ms. Carrillo stated she would forward relevant documents to the board for discussion on Day 2.

TASK 13

Ms. Carrillo will forward to the board additional information surrounding the pharmacist applicant's request.

Agenda Item 15 <u>Recess</u> Time: 4:29 p.m.

Ms. Lindemuth moved to recess the meeting at 4:29 p.m.until February 19, 2021 at 9:00, seconded by Ms. Long.

Off record for recess at 4:29 p.m.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing

Alaska Board of Pharmacy

DRAFT MINUTES OF THE EMERGENCY MEETING

February 18 - 19, 2021 Videoconference

By authority of AS 08.01.070(2), and in compliance with the provisions of AS 44.62, Article 6, a scheduled meeting of the Board of Pharmacy via videoconference on February 18 - 19, 2021. Due to the COVID-19 pandemic, in-person attendance was not available.

These are draft minutes and have not yet been approved by the board.

Agenda Item 1 **Call to Order/Roll Call** **Time: 9:10 a.m.**

The day 2, **February 19, 2021** videoconference was called to order by Chair, Rich Holt at 9:10 a.m.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Lana Bell, RPh #PHAP893
Tammy Lindemuth, Public Member (joined at 1:02 p.m.)
Sharon Long, Public Member (joined at 9:20 a.m.)
Justin Ruffridge, #PHAP1787

Division staff present:
Laura Carrillo, Executive Administrator
Lisa Sherrell, PDMP Manager
Bethany Carlile, Occupational Licensing Examiner
Melissa Dumas, Administrative Officer
Ilsa Lund, Alaska Board of Veterinary Examiners

Members from the public present/registered:

Pauline Henriques-Perry, Division of Legislative Audit
Brenda Walker, VA

Lauren Paul, CVS Health
Lisa Sherrell, State of Alaska
Jessica Adams, TelePharm
Molly Gray, Alaska Pharmacists Association
Ashley Schaber, Alaska Pharmacists Association/Alaska Native Tribal Health Consortium
James J Henderson (DLA), DLA
Caren Robinson, AkPhA
Lis Houchen, NACDS
Jennifer Adams, Idaho State University College of Pharmacy
Lorri Walmsley, Walgreens

Agenda Item 2 **Review/Approve Agenda** **Time: 9:11 a.m.**

Chair Holt reviewed the agenda for day 2. Ms. Carrillo informed the board that the AKPhA's modernization bill was uploaded to OnBoard. Chair Holt added that if the board wished to further discuss the license application withdrawal from the previous day, they could do so under executive session. Ms. Carrillo commented there is additional information regarding the remote order processing with PipelineRx. Ms. Carrillo also added she had requested DOL presence to discuss the Negative-Implication Canon, but that there it is likely an AAG won't be available due to other priorities.

On a motion duly made by Justin Ruffridge to approve the meeting agenda as amended by adding DOL discussion regarding PipelineRx, seconded by Lana Bell, and approved unanimously, it was:

RESOLVED to accept the February 19, 2021 meeting agenda as amended.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long				x

The motion passed with discussion from the board regarding returning to executive discussion for the purpose of discussing the withdrawal application. Dr. Ruffridge indicated from additional correspondence received, there is no need to further that discussion.

Agenda Item 3 **Ethics disclosures** **Time: 9:15 a.m.**

No ethics to disclose.

Agenda Item 4 **Public Comment 3** **Time: 9:17 a.m.**

Chair Holt clarified for the public that for the board's regulation discussion, there are two pieces related to regulations that previously closed for public comment; the board will not be able to entertain comments related to those subjects.

There was nobody on the line to provide public comment.

Agenda Item 5 **Regulations Overview** **Time: 9:18 a.m.**

Sharon Long joined the meeting at 9:20 a.m.

Ms. Carrillo provided documents for the board's reference relating to steps in the regulations process.

12 AAC 52.060 – 995 – ended 05/15/2020
This was included for reference; the board previously reviewed the public comments in May related to emergency regulations.

12 AAC 52.110 – ended 12/29/2020
No comments were received with these regulations relating to the emergency permit language and courtesy license language.

The Board reviewed the changes made to 12 AAC 52.110 expanding the existing emergency permit for pharmacists to include technicians and interns. A new section was also created for emergency courtesy licenses for pharmacists, technicians, and interns. Ms. Carrillo noted there were no public comments received by the deadline, December 29, 2020. The board's intent was to make these regulations permanent.

On a motion duly made by Justin Ruffridge to adopt the emergency regulations in 12 AAC 52.110 as permanent, seconded by Sharon Long and approved unanimously, it was:

RESOLVED to adopt the emergency regulations for 12 AAC 52.110 concerning emergency permits and courtesy licenses as permanent.

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x

James Henderson		x
Sharon Long	x	

The motion passed with no further discussion.

TASK 14

Ms. Carrillo will sign the affidavit of board action and certifying changes for the emergency to permanent regulation, 12 AAC 52.110, and will forward the documents to the regulations specialist.

12 AAC 52.855 – ended 02/11/2021

These regulations relate to the timeframe to register with the Prescription Drug Monitoring Program. The Board then reviewed public comments relating to the PDMP registration timeframe of 30 days. Chair Holt read out loud for the record each comment received, noting some comments were related to other PDMP topics and not specifically to the proposal. In considering comment from the Board of Veterinary Examiners, Chair Holt proposed separating the section referencing pharmacists in a new subsection so it was clear the language pertained only to this license group and not to other provider types. Chair Holt requested Regulations Specialist, Jun Maiquis to provide clarification on whether a new subsection could be created.

Jun Maiquis joined the room at 10:03 a.m. and clarified creating a subsection would not constitute a substantive change. No proposed changes were made to the language.

On a motion duly made by Lana Bell to accept 12 AAC 52.855 as amended, seconded by Justin Ruffridge and approved unanimously, it was:

> **RESOLVED to adopt the organizational amendment to the 30-day registration timeframe with the Prescription Drug Monitoring Program (PDMP).**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth				x
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion.

TASK 15
Ms. Carrillo will sign the affidavit of board action and certifying changes for the PDMP registration timeframe proposed in 12 AAC 52.855, and will forward the documents to the regulations specialist.

Agenda Item 8 **Join Medical Board for PDMP Discussion** **Time: 10:22 a.m.**

The board joined the State Medical Board to be present for Ms. Sherrell's PDMP board report and to be available to answer questions, if needed.

Agenda Item 7 **Outstanding Regulation Projects** **Time: 11:06 a.m.**

Upon return to the record, the board and Ms. Carrillo praised Ms. Sherrell for her excellent update to the State Medical Board. Ms. Carrillo performed a roll call.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Tammy Lindemuth, Public Member
Sharon Long, Public Member
Justin Ruffridge, #PHAP1787
Lana Bell, RPh #PHAP893

The board addressed the outstanding regulation projects.

PDMP
The board reviewed the outstanding regulations language in the document included in the packet. Dr. Ruffridge returned to the discussion on security of email when using the PDMP. Ms. Carrillo recalled previous discussions regarding limitations on requiring an employer-issued email; some licensees may not have a job in place yet or they may change employers. Dr. Ruffridge's primary concern was around security, expressing it would be helpful to use a two-factor authentication. Ms. Carrillo stated there could be a change to the current 180-day frequency of changing one's password; another option would be to send periodic reminders not to automatically allow their computer from remember login information. Ms. Sherrell's preference would be that people use it in the right way, that security shouldn't be compromised for convenience. Ms. Sherrell added that provider authentication is a method to verify security on the vendor end with Gateway integrations. Ms. Carrillo was unsure of whether two-factor authentication could co-exist with provider authentication.

TASK 16
Ms. Sherrell will request clarification from Appriss as to whether two-factor authentication is used successfully in other states.

Ms. Sherrell added there is a clear issue with not reviewing patient data. Dr. Ruffridge provided some insight that a physician is not going to review a PDMP unless you sit right there and have them do it. Ms. Carrillo also indicated this was a barrier identified at a recent pain closure workshop, highlighting the two schools of thought around why use isn't happening; whether it is no integration of the EHR or no ability for delegates to be CMAs. Ms. Sherrell clarified that delegates can still query the PDMP, but not directly within the HER; they would have to go directly to the PDMP site.

The board began discussing next changes to PDMP regulations, including a separate section for PDMP renewal.

Chair Holt called for lunch at 12:01 p.m.

Off record at 12:01 p.m.
On record at 1:04 p.m.

Agenda Item 10 Lunch **Time: 12:01 p.m.**

Upon return from lunch, Ms. Carrillo performed a roll call.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Tammy Lindemuth, Public Member
Justin Ruffridge, #PHAP1787
Lana Bell, RPh #PHAP893

Agenda Item 7 Outstanding Regulation Projects **Time: 1:04 p.m.**

PDMP
The board then discussed changed in employment and dispensing status. Ms. Carrillo recalled the discussion from the previous day and how a pharmacy should notify the department within a certain number of days following a change in dispensing or distributing status. Ms. Bell inquired whether pharmacies are asked to indicate their dispensing or distributing status, to which Ms. Carrillo confirmed.

The board returned to discussing whether the board should require all pharmacists to register regardless of whether they're dispensing. Chair Holt recalled the board previously held a discussion on requiring everyone to register, but the board overwhelmingly felt charging every pharmacist to use the database wasn't the intent. Ms. Sherrell pulled statistics showing more pharmacists are registered with the PDMP than are required to be.

The board continued discussing potential regulation changes for the PDMP, including delegate access, which isn't explicitly mentioned in the regulations currently, similar to "zero reporting."

Chair Holt called for recess at 2:24 p.m.

Off record at 2:24 p.m.
On record at 2:30 p.m.

Upon return from lunch, Ms. Carrillo performed a roll call.

Board members present, constituting a quorum:

Richard Holt, PharmD #PHAP2008, MBA – *Chair*
Leif Holm, PharmD #PHAP1606 – *Vice Chair*
Tammy Lindemuth, Public Member
Justin Ruffridge, #PHAP1787
Lana Bell, RPh #PHAP893
Sharon Long, Public Member

Medications to EMS

Chair Holt addressed medications to Emergency Medical Services (EMS), acknowledging the board doesn't currently have any language addressing this in 12 AAC 52. Ms. Bell provided insight into medication allocations to the local fire department/EMS as there is an existing practice for this that falls under DHSS's Medical Services Division. Ms. Bell clarified it is the state medical director who can issue directives, and those directives can be prescriptions given at the direction of Dr. Michael Levy, Director of EMS. Dr. Ruffridge agrees with Ms. Bell that this falls under DHSS, adding it is under Title 7, Chapter 26, Section 650. Dr. Ruffridge also agrees with Chair Holt that a simple regulation writing would clear up gray area around what's required.

TASK 17
Ms. Carrillo will follow-up with the pharmacist inquiring about medications to fire departments/EMS and will provide information on where to learn more about DHSS' Medical Services division.

Agenda Item 12 Potential Statute Changes Time: 2:44 p.m.

Dr. Ruffridge went through the AKPhA's modernization bill, which was previously reviewed by the board during their last meeting. Dr. Ruffridge clarified it has not yet been introduced, but the intent is to mobilize pharmacists, to promote pharmacist independence, and to adopt language around prescribing and administering, whether that's vaccines or emergency medications. Dr. Ruffridge directed the board to potentially the most significant part of the proposal, section 8, where a pharmacist may be able to provide patient care services. Section 11 is the section around adding pharmacists to unfair discrimination. Dr. Ruffridge recalled the negative implication canon

and whether the proposed changes to section 4 and 5 adding the ability for pharmacists to prescribe vaccines and emergency medications would effectively limit pharmacists from prescribing other drugs.

Ms. Carrillo inquired whether this proposal of section 8 for patient care services can be incorporated into the board's existing language for collaborative practice agreements, and to create a separate section for patient care services, then amending the definition of pharmacist to include patient care services. Ms. Bell stated that we are now able to perform testing under CLIA, so asked for clarification as to what the end goal is: Is it to limit us to just providing information by testing, vaccinating, and ordering, or is our goal to try to expand on our ability to test and treat with the intent of follow-up with another provider. Dr. Ruffridge stated it's open-ended; the goal being that the board of pharmacy should create compensable abilities for pharmacies. In the process of COVID response, Dr. Ruffridge recalled there were areas where the board was limited; one of those areas was around testing. Dr. Ruffridge added that if you can statutorily put something in place where a pharmacist can do x, and that falls under the jurisdiction of the board, the board can define that further in regulation.

Ms. Long's interpretation is that the proposed language indicates you can provide care for anything that doesn't require a new diagnosis. Chair Holt agreed, stating that if you look through the lens of the negative implication canon, you wouldn't be able to treat a condition for a *new* diagnosis, based on strep test, for example.

Chair Holt added that the current collaborative practice authority allows us to initiate or modify a drug therapy with a practitioner, whether it is new or existing. Whereas, if the proposed language says that "…AND for a condition that doesn't require a new diagnosis…", this is much more limiting than what our current laws says. Ms. Gray provided feedback that there's two ideas: one can be struck since it's indicating what is currently the process now. The AKPhA's intention is to make sure that the medical board/association was clear in what was trying to be accomplished. Other school of thought is to strike (a), and just include (b): a pharmacist may independently provide patient care services as defined by the board of pharmacy.

Chair Holt clarified that a bill generally is to seek from the legislature authority for which you don't already have; however, subsection (a) essentially is asking for authority to enter into a collaborative practice agreements, which is in pharmacists' existing authority. Chair Holt added that scope of practice is defined by the legislature, and not by the board, and that it seems the goal of this part of the bill is to seek authority to provide patient care services. Dr. Ruffridge added that what we don't have is a statutory connection is what we can provide under a collaborative practice agreement *and* compensation. Dr. Schaber also commented to clarify that the intent of the subsection (a) was not to make it more restrictive, but that the goal is to include "patient care services" from a reimbursement perspective; to be able to get reimbursed either under a collaborative practice agreement or independently. Dr. Wadsworth from UAA commented that if CLIA can be used to guide pharmacists in testing, we don't want pharmacists to wait for

collaborative practice agreements to be able to provide patient care services for general health and wellness, disease prevention, and optimization of medication therapy.

Dr. Adams from Idaho University and the UAA pharmacy program, who teaches law, clarified that in the statute on powers and duties of the board in AS 08.80.030, this could be amended to include patient care services. Ms. Carrillo suggested adding language to AS 08.80.030 to require the board adopt regulations around patient care services Ms. Bell stated she agreed with the feedback was not sure if the language was properly worded.

On a motion duly made by Richard Holt to support the pharmacy mobilization bill that the AKPhA has drafted, version 32-LS0468\A, regarding the pharmacy mobilization act and to support sections 1 through 11 of the bill, seconded by Leif Holm and approved unanimously, it was:

> **RESOLVED to support version 32-LS0468\A of the AKPhA's draft legislation on pharmacy mobilization.**

	APPROVE	DENY	ABSTAIN	ABSENT
Leif Holm	x			
Richard Holt	x			
Justin Ruffridge	x			
Lana Bell	x			
Tammy Lindemuth	x			
James Henderson				x
Sharon Long	x			

The motion passed with no further discussion; however, it was clarified during the motion that Dr. Ruffridge was voting as a board member and not as a participant in assisting the AKPhA with this draft legislation.

Ms. Carrillo inquired who would be representing the board in testifying to support this legislation. Chair Holt and Dr. Ruffridge volunteered.

Agenda Item 13 <u>Public Comment 4</u> Time: 4:15 p.m.

There were no public comments.

Agenda Item 11 <u>Return to Regulations</u> Time: 4:17 p.m.

The board returned to the discussion around PipelineRx. Ms. Carrillo also informed the board it was clarified there would not be an AAG present to discuss the Negative Implication Canon. Dr.

Holm commented that it seems the non-resident pharmacy is performing remote order entry, so essentially is acting and performing like a remote pharmacy.

The board discussed the legal guidance and ultimately requested Ms. Carrillo follow-up for clarification. Dr. Ruffridge assisted with crafting the follow-up question: Can a non-resident pharmacy registered in Alaska but located outside of the state provide remote pharmacy services in the state of Alaska? The board acknowledged a pharmacy must be registered in Alaska if providing any services to patients located in the state, but it is unclear whether that pharmacy can offer remote pharmacy services directly or through an Alaska-licensed pharmacist also located outside of the state but providing that service remotely.

TASK 18
Ms. Carrillo will follow-up with DOL on remote order entry services performed my out-of-state pharmacies.

The board then discussed next potential meeting dates and landed on May and September.

TASK 19
Ms. Carrillo will poll the board for available meeting dates in May and September.

Agenda Item 9 **<u>Adjourn</u>** **Time: 4:49 p.m.**

On a motion duly made by Tammy Lindemuth, seconded by Lana Bell, and approved unanimously to adjourn the meeting, the meeting was adjourned at 4:49 p.m.

_____
Laura Carrillo, Executive Administrator Date

_____
Richard Holt, Chair Date

PDMP

Alaska Prescription Drug Monitoring Program
Summary Prepared for the Board of Pharmacy
May 2021

This report contains summary data from the Prescription Drug Monitoring Program (PDMP). Data is provided as a courtesy for the board and is intended to be used for informational purposes only.

Notices

- The new Appriss contract started April 1st. Updated user manuals and dispensation guides will be uploaded soon to pdmp.alaska.gov.
- License integration is tentatively scheduled to go live on June 15th. Need to upgrade the specifications to include the newly created license types.

There are differences in the number of pharmacists licensed by the Board of Pharmacy and the number of pharmacists registered in the PDMP. The registration counts in the federal user role categories also include non-Alaska licensed pharmacists and some Alaska-licensed pharmacists have opted to register even though not required to by statute and regulations.

Registration

Portal (Professional license system)

Number of licensed Pharmacists: 1,082 (increase of 42 licenses)
Number of PDMP Pharmacist registrations: 736 (increase of 18 registrations)
Number of Pharmacists dispensing: 716 (increase of 78 pharmacists)

AWARxE (PDMP)

Number registered with the PDMP: 987
- Pharmacists – 770
- PIC – 90
- IHS Dispenser – 112
- VA Dispenser - 15

Delinquent Reporters

- Letters sent to 17 licensees in April for Q2 2021
  - 10 dispensers responded to obtain list of delinquent dates
  - 3 providers responded to clarify they are not dispensing
- 25 licensees appeared on the list for the second time and 18 of these had not replied to the first communication
- No letter has been sent to the pharmacies on the list for the second time pending more work with Appriss on the system limitations. (Meeting on Tuesday, May 11th)

Recommendations

- Encourage the use of authorized delegates.
- Encourage licensees to verify their user roles and specialties in AWARxE to improve the accuracy of reporting.

Recommendations to Prescribing Boards

- Encourage increased reviewing, including the use of authorized delegates.
- Issue periodic reminders to licensees on mandatory reviewing and reporting.
- Provide guidance to licensees on prescribing practices related to the use of dangerous combinations.

Contact: Lisa Sherrell | PDMP Manager| akpdmp@alaska.gov | 907-465-1039

- Providers should be notified they are not able to prescribe federally scheduled II and III controlled substances until their registration in AWARxE has been approved.
- Set daily MME in regulation.
- Develop a plan for following up with delinquent reporters.

Contract Updates

- A Communications Module allowing provider-to-provider communication within the PDMP will be launched soon. The quick start guide is complete, and instructions will be in the updated AWARxE user manual. Launch date TBD.
- We were recently notified of additional grant funding available to purchase the Provider Outlier Module. This module will identify prescribers whose prescribing habits could potentially have negative repercussions on their patients.
- We are discussing the Delinquent Reporting Notice with the states who have implemented the system and are anticipating enabling this feature once license renewals have completed. This enhancement will send notices to providers when at least one day of reporting is missed.

INV.
REPORT

THE STATE of ALASKA

Department of Commerce, Community, and Economic Development

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

550 West Seventh Avenue, Suite 1500
Anchorage, AK 99501-3567
Main: 907.269.8160
Fax: 907.269.8156

MEMORANDUM

DATE: May 06, 2021

TO: Board of Pharmacy

THRU: Greg Francois, Chief Investigator DS

FROM: Michael Bowles, Investigator DS MPB

RE: Investigative Report for the May 20, 2021 Meeting

The following information was compiled as an investigative report to the Board for the period of February 05, 2021 thru May 06, 2021; this report includes cases, complaints, and intake matters handled since the last report.

Matters opened by the Paralegals in Anchorage and Juneau, regarding continuing education audits and license action resulting from those matters are covered in this report.

OPEN - 37

Case Number	Violation Type	Case Status	Status Date
OUT OF STATE PHARMACY			
2021-000049	Violation of licensing regulation	Complaint	03/03/2021
2021-000232	Violation of licensing regulation	Complaint	04/02/2021
2021-000244	Violation of licensing regulation	Complaint	04/02/2021
2020-000360	Violation of licensing regulation	Investigation	03/11/2021
2020-000530	Violation of licensing regulation	Investigation	04/21/2021
2020-000602	Violation of licensing regulation	Investigation	03/23/2021
2020-000831	Falsified application	Investigation	04/07/2021
2020-000870	Falsified application	Investigation	04/06/2021
2020-000886	Violation of licensing regulation	Investigation	03/23/2021
2020-000972	Violation of licensing regulation	Investigation	04/21/2021

2020-000973	Falsified application	Investigation	03/11/2021
2020-001002	Falsified application	Investigation	03/23/2021
2020-001026	License application problem	Investigation	05/04/2021
2020-001084	Violation of licensing regulation	Investigation	05/05/2021
2021-000054	License application problem	Investigation	04/28/2021
2021-000100	License application problem	Investigation	03/23/2021
2021-000110	License application problem	Investigation	04/28/2021
2021-000111	License application problem	Investigation	04/13/2021
2021-000113	License application problem	Investigation	04/28/2021

PHARMACIST

2020-000655	Unprofessional conduct	Complaint	02/04/2021
2021-000164	Unprofessional conduct	Complaint	03/04/2021
2017-000092	Substance abuse	Investigation	02/15/2017
2021-000101	Falsified application	Investigation	03/23/2021

PHARMACY

2020-001086	Violation of licensing regulation	Complaint	03/03/2021
2021-000288	Violation of licensing regulation	Complaint	05/06/2021
2020-000359	Violation of licensing regulation	Investigation	02/24/2021
2020-000790	Violation of licensing regulation	Investigation	04/21/2021
2020-001003	PDMP Violation: Failure to Report	Investigation	05/05/2021
2021-000163	Violation of licensing regulation	Investigation	04/06/2021

PHARMACY TECHNICIAN

2019-000936	Falsified application	Monitor	04/23/2021
2019-000721	Falsified application	Investigation	02/09/2021
2021-000085	Continuing education	Investigation	02/10/2021
2021-000087	Continuing education	Investigation	02/23/2021

REGISTERED NURSE

2021-000380	Drug diversion	Intake	04/30/2021

WHOLESALE DRUG DEALER

2021-000245	Violation of licensing regulation	Complaint	04/02/2021
2020-000112	Unlicensed practice or activity	Investigation	04/16/2021
2020-001064	Violation of licensing regulation	Investigation	03/17/2021

Closed - 37

Case #	Violation Type	Case Status	Closed	Closure
OUT OF STATE PHARMACY				
2020-001065	Unethical conduct	Closed-Intake	02/05/2021	Incomplete Complaint
2020-001153	License application problem	Closed-Intake	02/22/2021	Review Complete
2020-001154	License application problem	Closed-Intake	02/22/2021	Review Complete
2021-000050	License application problem	Closed-Intake	02/22/2021	Review Complete
2021-000180	Violation of licensing regulation	Closed-Intake	03/11/2021	No Action - No Violation
2020-000343	License application problem	Closed-Complaint	03/01/2021	Review Complete
2020-000361	Violation of licensing regulation	Closed-Complaint	03/05/2021	No Action - No Violation
2020-000776	License application problem	Closed-Complaint	04/19/2021	No Action - No Violation
2020-000797	License application problem	Closed-Complaint	03/24/2021	
2020-000917	Falsified application	Closed-Complaint	04/19/2021	No Action - No Violation
2020-000346	Violation of licensing regulation	Closed-Investigation	04/23/2021	Advisement Letter
2021-000182	Violation of licensing regulation	Closed-Investigation	04/23/2021	Advisement Letter
PHARMACIST				
2019-001356	PDMP Violation: Failure to Register	Closed-Complaint	02/16/2021	No Action - Minor Offense
2019-001357	PDMP Violation: Failure to Register	Closed-Complaint	02/16/2021	No Action - No Violation
2019-001360	PDMP Violation: Failure to Register	Closed-Complaint	02/12/2021	No Action - Minor Offense
2019-001369	PDMP Violation: Failure to Register	Closed-Complaint	03/05/2021	No Action - No Violation

2019-001370	PDMP Violation: Failure to Register	Closed-Complaint	02/16/2021	No Action - Minor Offense
2019-001375	PDMP Violation: Failure to Register	Closed-Complaint	02/12/2021	No Action - No Violation
2019-001376	PDMP Violation: Failure to Register	Closed-Complaint	02/16/2021	No Action - Minor Offense
2020-000001	PDMP Violation: Failure to Register	Closed-Complaint	02/18/2021	No Action - No Violation
2017-000557	Unprofessional conduct	Closed-Investigation	03/05/2021	License Action
2019-001359	PDMP Violation: Failure to Register	Closed-Investigation	02/16/2021	Advisement Letter
2019-001365	PDMP Violation: Failure to Register	Closed-Investigation	02/16/2021	Advisement Letter
2019-001367	PDMP Violation: Failure to Register	Closed-Investigation	02/12/2021	Advisement Letter
2019-001368	PDMP Violation: Failure to Register	Closed-Investigation	02/16/2021	Advisement Letter
2020-000002	PDMP Violation: Failure to Register	Closed-Investigation	02/12/2021	Advisement Letter
2020-000003	PDMP Violation: Failure to Register	Closed-Investigation	02/12/2021	Advisement Letter
2021-000082	Continuing education	Closed-Investigation	03/04/2021	No Action - No Violation
2021-000089	Continuing education	Closed-Investigation	04/01/2021	No Action - No Violation

PHARMACY

2018-001285	Negligence	Closed-Investigation	03/09/2021	Advisement Letter

PHARMACY TECHNICIAN

2021-000083	Continuing education	Closed-Intake	02/11/2021	No Action - No Violation
2021-000086	Continuing education	Closed-Intake	02/19/2021	No Action - No Violation
2021-000079	Continuing education	Closed-Complaint	03/09/2021	No Action - No Violation
2021-000076	Continuing education	Closed-Investigation	03/03/2021	No Action - No Violation
2021-000077	Continuing education	Closed-Investigation	04/14/2021	No Action - No Violation
2021-000078	Continuing education	Closed-Investigation	04/14/2021	No Action - No Violation

WHOLESALE DRUG DEALER

2021-000233	Violation of licensing regulation	Closed-Investigation	04/23/2021	Advisement Letter

END OF REPORT

BOARD BUSINESS

ALASKA BOARD OF PHARMACY
2021 STRATEGIC PLAN

The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

GUIDING PRINCIPLES	GOALS	STRATEGIES
COMMUNICATION	**1.** Engage in effective communication and promote transparency of public information.	**1.1** Improve customer service by providing timely updates to applicants and licensees. **1.2** Encourage appropriate disclosure of information related to licensing and investigative processes. **1.3** Maximize communication channels through the Board of Pharmacy website and List Service. **1.4** Increase collaboration with health care licensing boards and key stakeholders to address important health issues.
ADMINISTRATION	**2.** Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	**2.1** Avoid delays in application processing by maintaining adequate staffing and exploring retention strategies. **2.2** Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process. **2.3** Automate licensure through online applications. **2.4** Exercise fiscal discipline through effective budget management.
LICENSURE	**3.** Ensure competency and qualifications prior to licensure and renewal.	**3.1** Adhere to established licensing standards by reviewing education, experience, and examination requirements. **3.2** Periodically review applications and forms for alignment with existing requirements.
REGULATION & ENFORCEMENT	**4.** Grow the economy while promoting community health and safety.	**4.1** Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety. **4.2** Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP). **4.3** Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance. **4.4** Establish disciplinary guidelines and conduct random audits to ensure safety protocols and competencies are met. **4.5** Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arises.

For more information, please visit the following resources:

Board of Pharmacy Homepage: pharmacy.alaska.gov
Prescription Drug Monitoring Program (PDMP): pdmp.alaska.gov

Email: pharmacy@alaska.gov
Phone: 907-465-1073

Annual Report

Fiscal Year 2020

Alaska Board of Pharmacy

Department of Commerce, Community and Economic Development

Division of Corporations, Business and Professional Licensing

This annual performance report is presented in accordance with Alaska statute AS 08.01.070(10).

Its purpose is to report the accomplishments, activities, and the past and present needs of the licensing program.

Alaska Board of Pharmacy
FY 2020 Annual Report

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Alaska Board of Pharmacy
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Identification of the Board

Board Member	Duty Station	Date Appointed	Term Expires
Richard Holt, PharmD, MBA Chair	Eagle River, AK	Mar 01, 2016	Mar 01, 2024
Leif Holm, PharmD Vice-Chair	North Pole, AK	Mar 01, 2015	Mar 01, 2023
Lana Bell, RPh Secretary	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
James Henderson, RPh	Soldotna, AK	Mar 01, 2017	Mar 01, 2021
Justin Ruffridge, PharmD	Anchorage, AK	Mar 01, 2020	Mar 01, 2022
Sharon Long, Public Member	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
Tammy Lindemuth, Public Member	Anchorage, AK	Jan 24, 2018	Mar 01, 2021

Alaska Board of Pharmacy
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Identification of Staff

Laura Carrillo, MPH – Executive Administrator
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Lisa Sherrell – Prescription Drug Monitoring Program Manager (since January 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Heather Noe – Licensing Examiner (since January 2020)
Tracy Wiard – Licensing Examiner (since March 2020)
Deborah Roesch – Licensing Examiner (until March 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Carl Jacobs – Investigator III
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Anchorage, Alaska 99811-0806
(907) 465-2550

Jun Maiquis, Regulations Specialist
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Alaska Board of Pharmacy
FY 2020 Annual Report

Narrative Statement

Overview:
The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare of by and through the effective control and regulation of the practice of pharmacy in the State. During FY2020, the board of pharmacy continued its efforts to support the pharmaceutical supply chain; the board expanded regulation of its profession by licensing out-of-state wholesale drug distributors, outsourcing facilities, and third-party logistics providers effective October 31, 2019, bringing the number of regulated license types from seven (7) to ten (10). Other license category types are in-state pharmacies, out-of-state pharmacies, remote pharmacies, drug rooms, in-state wholesale drug distributors, pharmacists, pharmacist interns, and pharmacy technicians. Additionally, the board regulates shared pharmacy services and telepharmacy systems, approves collaborative practice agreements, and oversees the state's controlled substance prescription database, the Prescription Drug Monitoring Program (PDMP). From FY2019 to FY2020, the board grew its license base with an increase of 17.25% in new licensees and expanded the PDMP with a 7.9% increase in new users.

The board is statutorily required to meet at least three (3) times per year either in person or telephonically. In FY2020, the board held four (4) regular board meetings. To save on travel, hotel, and per diem costs, 2 of the 4 meetings were held via videoconference, and 1 meeting was held via teleconference due to travel restrictions; this saved the board an average of $9,000. Through the development of dedicated subcommittees this year, the board also began concerted efforts to reduce regulatory barriers, identify outdated regulations, and assess simplification of licensure. Additionally, the board began work on its strategic plan to formally identify values, goals, and strategies to guide the board in continuing its adherence to promoting, preserving and protecting the health, safety, and welfare of the public. The board has identified the following focus areas for this plan: communication, administration, regulation and legislation, licensure, and enforcement.

The Board of Pharmacy maintains its membership with the National Association of Boards of Pharmacy (NABP) and the National Association of Controlled Substance Authorities (NASCA), which provide the board with industry support and access to national resources, many of which provide administrative efficiency and support to the board in avoiding redundant services and lowering costs to the State, prospective applicants, and licensees. Through its membership with the NABP and at no additional cost, the board of pharmacy is able to delegate administration of its state jurisprudence exam for pharmacist licensure and reporting of disciplinary actions to the association. The NABP also provides an ePortal service for transfer of national examination scores and state licenses, a continuing education monitoring service, and intrastate and interstate datasharing hubs to facilitate exchange of data through the PDMP. Through its membership with NASCA, the board has access to discussion forums and comprehensive state information to assist in curtailing the abuse, misuse, and diversion of controlled substances.

Both memberships also give the board the opportunity to apply for travel and conference scholarships. The board of pharmacy also continues to participate in examination writing workshops at the NABP headquarters in Illinois to ensure the current pool of Multistate Jurisprudence Pharmacy Examination (MPJE) questions required for pharmacist licensure are relevant. In FY2020, the board planned to send Tammy Lindemuth to the MPJE writing workshop, but was unable to attend due to the COVID-19 pandemic. Though there is a remote attendance option, the board recognizes challenges in effective participation via distance writing.

Also during FY2020, the board of pharmacy responded quickly to the rapidly evolving regulatory challenges and needs posed by the 2019 novel coronavirus pandemic. Through two emergency teleconferences and an accompanying regulations project, the board made amendments to their emergency preparedness regulations, providing an alleviation of regulatory barriers to practice, allowing the provision for adequate personnel resources through expansion of delegable duties, and streamlining application processes. Additionally, the board released a series of guidance to licensees to assist in responding to the public health crisis. The board also worked collaboratively with the Alaska State Medical Board and Board of Nursing to issue comprehensive guidance.

Board meetings held:

- March 7 – 8, 2019 (Teleconference; Anchorage for those in-area)
- November 14 – 15, 2019 (Teleconference; Anchorage for those in-area)
- February 7 – 8, 2020 (Anchorage)
- May 7 – 8, 2020 (Teleconference; no public attendance due to COVID-19)
- May 28, 2020 (Teleconference; reviewed public comment to make emergency regulations permanent)

Emergency meetings held:

- March 23, 2020 (Teleconference; no public attendance due to COVID-19)
- March 27, 2020 (Teleconference; no public attendance due to COVID-19)

Regulation projects:

I. The board continued to work towards improving regulations and implemented new sections for the new license categories. New regulations and amendments to the following sections went into effect on October 31, 2019:

- 12 AAC 52.010 – Classification of licensure
- 12 AAC 52.050 – Closed pharmacies
- 12 AAC 52.070 – Application for pharmacist license by examination
- 12 AAC 52.095 – Application for pharmacist license by reciprocity
- 12 AAC 52.110 – Emergency pharmacist permit
- 12 AAC 52.120 – Review of pharmacist intern license application
- 12 AAC 52.150 – Proof of licensure for individual pharmacists working for tribal health programs
- 12 AAC 52.220 – Pharmacist interns
- 12 AAC 52.240 – Pharmacist collaborative practice authority
- 12 AAC 52.340 – Approved programs
- 12 AAC 52.423 – Remote pharmacy license
- 12 AAC 52.425 – Telepharmacy system for a remote pharmacy
- 12 AAC 52.465 – Controlled substance prescription drug orders
- 12 AAC 52.500 – Transfer of a prescription drug order

- 12 AAC 52.510 – Substitution
- 12 AAC 52.530 – Return or exchange of drugs
- 12 AAC 52.610 – Wholesale drug distributor license
- 12 AAC 52.696 – Outsourcing facilities
- 12 AAC 52.697 – Third-party logistics providers
- 12 AAC 52.925 – Grounds for denial or discipline for criminal history
- 12 AAC 52.985 – Emergency preparedness
- 12 AAC 52.993 – Executive administrator
- 12 AAC 52.995 – definitions

II. The board is also continuing to work regulations that reflect current standards and practices of pharmacy, and that also reduce practice and process barriers. Regulations included in the board's simplification project include:

- 12 AAC 52.020 – Pharmacy license
- 12 AAC 52.060 – Fire or other disaster
- 12 AAC 52.075 – Good moral character
- 12 AAC 52.080 – Internship requirements for a pharmacist license
- 12 AAC 52.095 – Application for pharmacist license by reciprocity
- 12 AAC 52.100 – Temporary pharmacist license
- 12 AAC 52.110 – Emergency pharmacist permit
- 12 AAC 52.120 – Pharmacist interns
- 12 AAC 52.140 – Pharmacy technicians
- 12 AAC 52.200 – Pharmacist-in-charge
- 12 AAC 52.210 – Pharmacist duties
- 12 AAC 52.220 – Pharmacist intern requirements
- 12 AAC 52.230 – Pharmacy technician requirements
- 12 AAC 52.240 – Pharmacist collaborative practice agreements
- 12 AAC 52.250 – Job shadowing in a pharmacy
- 12 AAC 52.300 – License renewal
- 12 AAC 52.310 – Reinstatement of an expired pharmacist or pharmacy technician license
- 12 AAC 52.400 – General guidelines for pharmacies
- 12 AAC 52.415 – Prescription drug dispensing machines (new section)
- 12 AAC 52.420 – Security
- 12 AAC 52.423 – Remote pharmacy license
- 12 AAC 52.430 – Sterile compounding
- 12 AAC 52.440 – Non-sterile compounding
- 12 AAC 52.444 – Approval for shared pharmacy services by pharmacist (new section)
- 12 AAC 52.470 – Refills
- 12 AAC 52.475 – Dispensing refills in a declared emergency
- 12 AAC 52.480 – labeling
- 12 AAC 52.490 – Prescriptions by electronic transmission
- 12 AAC 52.500 – Transfer of a prescription drug order
- 12 AAC 52.510 – Substitution
- 12 AAC 52.530 – Return or exchange of drugs
- 12 AAC 52.535 – Independent prescribing & administration of vaccines & related emergency medications

- 12 AAC 52.536 – Independent prescribing & dispensing of opioid overdose drugs by pharmacists
- 12 AAC 52.550 – Advertising
- 12 AAC 52.560 – Destruction and disposal of drugs
- 12 AAC 52.570 – Drug regimen review
- 12 AAC 52.580 – Data processing systems
- 12 AAC 52.585 – Patient counseling
- 12 AAC 52.590 – Prepackaging of drugs for practitioner offices
- 12 AAC 52.696 – Outsourcing facilities
- 12 AAC 52.697 – Third-party logistics providers
- 12 AAC 52.730 – Drug distribution and control
- 12 AAC 52.800 – Drug room license & pharmacist requirements
- 12 AAC 52.970 – Reinstatement of a suspended or revoked license
- 12 AAC 52.985 – Reporting requirements to the board
- 12 AAC 52.990 – Display or proof of license
- 12 AAC 52.991 – Disciplinary decision or conviction reporting requirement

III. The also board adopted emergency regulations in response to COVID-19 effective April 3, 2020. During their May 28th meeting, the board moved to make emergency regulations permanent. The intent of these regulations are to alleviate workload strain and support adequate staffing by:

- Increasing capacity by expanding the tasks which a pharmacy technician who holds a national certification may perform;
- Allowing a cashier or bookkeeper to work in a pharmacy without being licensed as a technician;
- Decreasing unnecessary administrative requirements;
- Increasing the ranks of licensees who may provide immunizations during the emergency by removing the requirement to obtain CPR certification;
- Expanding shared pharmacy service functions;
- Clarifying pharmacists and pharmacist interns may administer drugs pursuant to an Rx drug order;
- Allowing for temporary relocations during the emergency without applying for a new license; and
- Allowing the distribution, if insurance allows, of sufficient medication to avoid forcing patients to make multiple return trips.

Potential Legislative Priorities:

- Removing burdensome and obsolete statutes to improve licensure and administrative efficiency and to support adequate and efficient personnel staffing
- Seek amendments to Title 21 to recognize pharmacists as providers to allow for reimbursement for services related to ordering and administering tests

Other:

- Tammy Lindemuth has been delegated by board chair, Rich Holt, to serve as chair of the Controlled Substance Advisory Committee (CSAC) and continues to collaborate with its members to meet the committee's goals and objectives
- The board continues to partner with the Alaska Pharmacists Association (AKPhA) to accomplish the shared goals of advancing the pharmacy profession in the state
- The board continues to work towards convening a PDMP subcommittee with all affected boards to support a collaborative opioid response and to improve licensee compliance with mandatory use.

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Budget Recommendations for FY 2021

The Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
August 27 - 28, 2020	Anchorage/Teleconference	7	1
☒ Airfare:			$5,000.00
☒ Hotel:			$1,000.00
☒ Ground:			$100.00
☒ Other: M&IE			$900.00
Total Estimated Cost:			**$7,000.00**

Board Meeting Date	Location	# Board	# Staff
November 5 – 6, 2020	Anchorage/Teleconference	7	1
☒ Airfare:			$5,000.00
☒ Hotel:			$1,000.00
☒ Ground:			$100.00
☒ Other: M&IE			$900.00
Total Estimated Cost:			**$7,000.00**

Board Meeting Date	Location	# Board	# Staff
February 2021	Anchorage/Teleconference	7	1
☒ Airfare:			$5,000.00
☒ Hotel:			$1,000.00
☒ Ground:			$100.00
☒ Other: M&IE			$900.00
Total Estimated Cost:			**$7,000.00**

Board Meeting Date	Location	# Board	# Staff
May 2021	Anchorage/Teleconference	7	1
☒ Airfare:			$5,000.00
☒ Hotel:			$1,000.00
☒ Ground:			$100.00
☒ Other: M&IE			$900.00
Total Estimated Cost:			**$7,000.00**

Budget Recommendations for FY 2021 (continued)

Travel Required to Perform Examinations

☒ Not applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Conference:	$0.00
☐ Other:	$0.00
Describe "Other" (break out all sections):	
Total Estimated Cost:	**$0.00**

Out-of-State Meetings and Additional In-State Travel (Rank in order of importance)

☐ #1 Rank in Importance or ☐ Not Applicable

Date	Location	# Board	# Staff
September 9 -11, 2020	Mt. Prospect, IL	2	0

Description of meeting and its role in supporting the mission of the Board:

The NABP MPJE State Specific Review Meeting. This meeting requires two people from the Board of Pharmacy to attend to reviewed questions to include on the Alaska MPJE. The NABP direct-books for a total of $1,500.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$2,000.00	$0.00	$1,000.00	$3,000.00
☒ Hotel:	$300.00	$0.00	$500.00	$800.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$100.00	$0.00	$0.00	$100.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$2,500.00**	**$0.00**	**$1,500.00**	**$4,000.00**

Budget Recommendations for FY 2021 (continued)

Out-of-State Meetings and Additional In-State Travel

#2 Rank in Importance

Date	Location	# Board	# Staff
October 11 -13, 2020	Carefree, AZ	2	1

Description of meeting and its role in supporting the mission of the Board:

The NABP District 6, 7 & 8 Meeting is important to attend due to the detail work of the organization that is done at the district meeting, and a great networking opportunity with the other districts such as WA, OR, and ID to discuss regional issues of mutual concern as well as national issues. NABP has a travel grant for $1,500.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$2,000.00	$0.00	$1,000.00	$3,000.00
☒ Hotel:	$300.00	$0.00	$500.00	$800.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$100.00	$0.00	$0.00	$100.00
Describe "Other" (break out all sections):				
Net Total:	**$2,500.00**	**$0.00**	**$1,500.00**	**$4,000.00**

Out-of-State Meetings and Additional In-State Travel

#3 Rank in Importance

Date	Location	# Board	# Staff
April 5 – 8, 2021	Nashville, TN	1	2

Description of meeting and its role in supporting the mission of the Board:

National Rx Abuse and Heroin Summit – This conference supports the state's opioid response and the board's efforts to effectively administer the state's PDMP. Federal grant funds will be used to send 2 staff members to this conference to attend the PDMP track. License fees will be used to send 1 board member to attend the regulatory, policy, clinical, and/or law enforcement tracks.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$1,700.00	$0.00	$3,400.00	$5,100.00
☒ Hotel:	$750.00	$0.00	$1,500.00	$2,250.00
☒ Ground:	$100.00	$0.00	$100.00	$200.00
☒ Conference:	$0.00	$750.00	$0.00	$750.00
☒ Other	$335.00	$0.00	$670.00	$1,005.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$2,885.00**	**$750.00**	**$5,670.00**	**$9,305.00**

Budget Recommendations for FY 2021 (continued)

Out-of-State Meetings and Additional In-State Travel

#4 Rank in Importance

Date	Location	# Board	# Staff
October 26 – 29, 2020	Birmingham, AL	1	1

Description of meeting and its role in supporting the mission of the Board:

National Assocation of State Controlled Substances Authorities (NASCA) – The board supports trainig opportunities for its investigator and the PDMP manager. This opportunity would assist in advancing knowledge, skills, and abilities to support efforts to reduce drug misuse, abuse, and diversion.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$1,000.00	$0.00	$0.00	$1,000.00
☒ Hotel:	$1,100.00	$0.00	$0.00	$1,100.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$400.00	$0.00	$0.00	$400.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$2,600.00**	**$0.00**	**$0.00**	**$2,600.00**

Out-of-State Meetings and Additional In-State Travel

#5 Rank in Importance

Date	Location	# Board	# Staff
November 16 – 17, 2020	Arlington, VA	2	0

Description of meeting and its role in supporting the mission of the Board:

3rd Annual Compounding Pharmacy Compliance Conference – The board has been working on advancing their comounding regulations over the last few years. Attendance at this conference would be beneficial to these efforts, and has the ultimate goal of improving patient safety.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$1,500.00	$0.00	$0.00	$1,500.00
☒ Hotel:	$1,200.00	$0.00	$0.00	$1,200.00
☒ Ground:	$100.00	$0.00	$0.00	$100.00
☒ Conference:	$0.00	$0.00	$0.00	$0.00
☒ Other	$500.00	$0.00	$0.00	$500.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$3,300.00**	**$0.00**	**$0.00**	**$3,300.00**

Budget Recommendations for FY 2021 (continued)

Out-of-State Meetings and Additional In-State Travel

#6 Rank in Importance

Date	Location	# Board	# Staff
Multiple; TBD	Washington, D.C. + TBD	1	2

Description of meeting and its role in supporting the mission of the Board:

Conferences as required as a condition of receiving federal funding. The board of pharmacy is the recipient of a CDC and BJA grant, and must use funds to travel to grant recipient conferences. Federal funds will be used by staff and license fees will be used for board member travel.

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☒ Airfare:	$2,000.00	$8,000.00	$0.00	$10,000.00
☒ Hotel:	$1,000.00	$2,000.00	$0.00	$3,000.00
☒ Ground:	$200.00	$400.00	$0.00	$600.00
☒ Conference:	$1,000.00	$2,000.00	$0.00	$3,000.00
☒ Other	$500.00	$1,000.00	$0.00	$1,500.00
Describe "Other" (break out all sections):		M&IE		
Net Total:	**$4,700.00**	**$13,400.00**	**$0.00**	**$18,100.00**

Non-Travel Budget Requests

☒ Not Applicable ☐ Resources ☐ Examinations

☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

Budget Recommendations for FY 2021 (continued)

Other Items with a Fiscal Impact

Cost Per Event: **$0.00**

☒ **Not Applicable**

Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Summary of FY 2021 Fiscal Requests

Board Meetings and Teleconferences:	$28,000.00
Travel for Exams:	$0.00
Out-of-State and Additional In-State Travel:	$41,305.00
Dues, Memberships, Resources, Training:	$0.00
Total Potential Third-Party Offsets:	–$22,820.00
Other:	$0.00
Total Requested:	**$46,485.00**

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Legislation Recommendations Proposed Legislation for FY 2021

☐ **No Recommendations**
The Board has no recommendations for proposed legislation at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed legislation:

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall
(1) be fluent in the reading, writing, and speaking of the English language;
~~(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;~~
(3) be a graduate of a college in a degree program approved by the board;
(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person
(1) submits a written application to the board on a form required by the board;
(2) is at least 18 years of age;
~~(3) is of good moral character;~~
(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
(5) has engaged in the practice of pharmacy for at least one year ~~or has met the internship requirements of this state~~ within the one-year period immediately before applying for a license under this section;
(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;
(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and (8) pays all required fees.

Sec. 08.80.158 REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. REPEAL

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs or devices to a
(A) licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall
(1) obtain a license under AS 08.80.157;

CONTINUED ON FOLLOWING PAGE

(2) appoint an agent on whom process can be served in the state; and
(3) authorize inspection of the facility by a designee of the board under (c) of this section or

(B) consumer in this state, a pharmacy located outside of the state shall
(1) obtain a license under AS 08.80.157; and
(2) appoint an agent on whom process can be served in the state.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall
(1) register as an outsourcing facility with the United States Food and Drug Administration; and (2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may
(1) require an inspection of the applicant's facility located outside the state; and
(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:
(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer; (4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) ~~registration or~~ licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF~~ DRUGS ~~VACCINES AND RELATED EMERGENCY MEDICATIONS.~~

(1) A pharmacist may independently prescribe
(2) and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
(3) and dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
(4) and dispense dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
(5) and dispense epinephrine auto-injectors;
(6) and dispense drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:
(7) do not require a new diagnosis;
(8) are minor and generally self-limiting;
(9) have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
(10) in the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
(11) In this section,
(1) "opioid overdose drug" has the meaning given in AS 17.20.085;
(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

(a) The board shall not adopt any regulations authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist or person acting at the direction of a pharmacist shall disclose the price of filling any prescription when requested by the consumer.
(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.
(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under
(A) a health care insurance plan as defined under AS 21.54.500;
(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);
(C) a plan offered under AS 39.30.090 or 39.30.091;
(D) a federal governmental plan as defined under AS 21.54.500;
(E) the Medicaid or Medicare program; or
(F) a self-insured employer benefit plan;
(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.
(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.
(c) In this section, "regularly" means to dispense more than a 3-day supply to a patient.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," "apothecary", or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,
(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, ~~dosage form,~~ and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(30) "practice of pharmacy" means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the independent prescribing, dispensing and administration of ~~vaccines and related emergency medication; the independent dispensing of opioid overdose~~ drugs and devices in accordance with AS 08.80.168; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Regulation Recommendations Proposed Legislation for FY 2021

☐ **No Recommendations**
The Board has no recommendations for proposed regulations at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed regulations:

Regulation projects are ongoing and may change during FY2021.

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Goals and Objectives

Part I

FY 2020's goals and objectives, and how they were met:

Goal #1:
The board will continue to promote, preserve, and protect the public, safety, and welfare by and through the effective control and regulation of the practice of pharmacy. The board has a very aggressive list of regulations that will be reviewed and potentially finalized in FY 19 to advance this goal, including but not limited to:

1. Nationally certified pharmacy technicians
2. Tech-Check-Tech duties
3. Partial filling of Schedule II controlled substances
4. A regulation from FY 16 goal regarding licensees working for Tribal Health Programs
5. Executive Administrator qualifications and duties
6. Out of State wholesale, third party logistics providers and outsourcing facility licenses and regulations
7. Interchangeable biosimilar regulations (substitution)

Met by: Regulation projects and implemented changes (1 – 4). Legislative changes (5 – 7).

Goal #2:
The board will continue to provide input and comment on any proposed regulations involving medications, pharmaceutical care, or the practice of pharmacy.

Met by: Public comment periods held during board meetings and through written public comment opportunities.

Goal #3:
The board will continue to promote effective patient counseling by licensees.

Met by: Effective regulations and board guidance posted to its website.

Goal #4:
The board will continue to assess and evaluate the multi-state pharmacy jurisprudence examination (MPJE) and send two members to the MPJE Item Development workshop.

Met by: Participation at MPJE writing workshops.

Goals and Objectives (continued)

Part I (continued)

FY 2020's goals and objectives, and how they were met:

Goal # 5:
The board will continue to assess and evaluate the licensing of pharmacy technicians and discuss the introduction, recognition, and duties for a nationally certified pharmacy technician.

Met by: Regulation projects, including during emergency regulations, which will be made permanent.

Goal # 6:
The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

Met by: Including as a discussion item at board meetings.

Goal #7:
The board will continue its affiliation with the National Association of Boards of Pharmacy (NABP) and send one member to the District 7 NABP meeting and two members to the annual NABP meeting.

Met by: Renewed membership and continued participation in meetings and forum discussions.

Goal #8:
The board will continue to evaluate the impact of current regulations and the need for new regulations or amendments to current regulations to advance our mission.

Met by: Regulation projects, strategic planning, and subcommittee meetings.

Goal #9:
The board will continue to assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and support continuing funding and enhancement for the PDMP.

Met by: Continued monitoring of PDMP compliance, data evaluation, and submission of new Bureau of Justice Assistance grant.

Goal #10:
The board will monitor, assess, evaluate, and modify the Alaska PDMP based on the best interest of the public and profession.

Met by: Continued discussion amongst affected boards and constituents.

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Goals and Objectives

Part II

FY 2021's goals and objectives, and proposed methods to achieve them. Describe any strengths, weaknesses, opportunities, threats and required resources:

Goal #1:
The board will continue to promote, preserve, and protect the public, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Goal #2:
The board will continue to provide input and comment on any proposed regulations involving medications, pharmaceutical care, or the practice of pharmacy.

Goal #3:
The board will continue to promote effective patient counseling by licensees.

Goal #4:
The board will continue to assess and evaluate the multi-state pharmacy jurisprudence examination (MPJE) and send two members to the MPJE Item Development workshop.

Goal #5:
The board will continue to assess and evaluate the licensing of pharmacy technicians and discuss the introduction, recognition, and duties for a nationally certified pharmacy technician.

Goal #6:
The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

Goal # 7:
The board will continue its affiliation with the National Association of Boards of Pharmacy (NABP) and send one member to the District 7 NABP meeting and two members to the annual NABP meeting.

Goal #8:
The board will continue to evaluate the impact of current regulations and the need for new regulations or amendments to current regulations to advance our mission.

Goals and Objectives (continued)

Part II (continued)

FY 2021's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

Goal #9:
The board will continue to assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and support continuing funding and enhancement for the PDMP.

Goal #10:
The board will monitor, assess, evaluate, and modify the Alaska PDMP based on the best interest of the public and profession.

Goal #11:
The board will develop a strategic plan around communication, administration, regulation and legislation, licensure, and enforcement.

Goal #12:
The board will continue its affiliation and collaboration with the Alaska Pharmacists Association, including attendance at its annual meetings.

Goal #13:
The board will support its staff in participating at training opportunities and attendance at professional conferences, including training to support assigned investigators.

Goal #14:
The board will continue to simply its statutes and regulations by assessing outdated, burdensome, or unnecessary regulations.

Alaska Board of Pharmacy
Fiscal Year 2020 Annual Report

Sunset Audit Recommendations

Date of Last Legislative Audit:
Board Sunset Date:

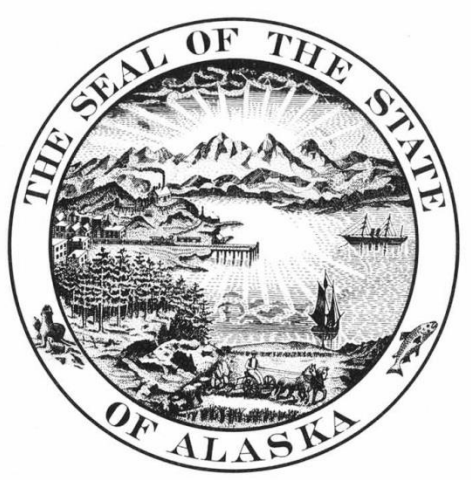
Audit Recommendation:	DCBPL's chief investigator should work with the director to improve the timeliness of investigations.
Action Taken:	A Standard Operating Procedure (SOP) was adopted to require investigative staff to enter case notes explaining any gaps between activities greater than sixty days. In addition, each member of staff is held accountable for timeliness of investigative actions.
Next Steps:	Monitor for effectiveness.
Date Completed:	January 5, 2018

Audit Recommendation:	DCBPL's director should improve procedures to ensure required licensure documentation is appropriately obtained and retained.
Action Taken:	The division will continue to provide training to staff to ensure they are aware of their roles and responsbilities in preserving an accurate and complete adminstrative record.
Next Steps:	
Date Completed:	

Annual Report

Fiscal Year 2021

Board of Pharmacy



Department of Commerce, Community and Economic Development

Division of Corporations, Business and Professional Licensing

This annual performance report is presented in accordance with Alaska statute AS 08.01.070(10).

Its purpose is to report the accomplishments, activities, and the past and present needs of the licensing program.

Board of Pharmacy
FY 2021 Annual Report

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Board of Pharmacy
FY 2021 Annual Report

Identification of the Board

Board Member	Duty Station	Date Appointed	Term Expires
Richard Holt, PharmD, MBA Chair	Eagle River, AK	Mar 01, 2020	Mar 01, 2024
Leif Holm, PharmD Vice Chair	North Pole, AK	Mar 01, 2015	Mar 01, 2023
Lana Bell, RPh Secretary	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
James Henderson, RPh	Soldotna, AK	Mar 01, 2017	Mar 01, 2025
Justin Ruffridge, PharmD	Anchorage, AK	Mar 01, 2020	Mar 01, 2024
Sharon Long Public Member	Anchorage, AK	Mar 01, 2018	Mar 01, 2022
Tammy Lindemuth Public Member	Anchorage, AK	Mar 01, 2018	Mar 01, 2025

Identification of the Board (continued)

Board Member	Duty Station	Date Appointed	Term Expires
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020
Insert Name Here Board Seat Title	City Location	Mar 01, 2018	Mar 01, 2020

Board of Pharmacy
FY 2021 Annual Report

Identification of Staff

Laura Carrillo, MPH – Executive Administrator
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Lisa Sherrell – Prescription Drug Monitoring Program Manager (since January 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Michael Bowles – Investigator III (since February, 2021)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Heather Noe – Licensing Examiner (since January 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Bethany Carlile – Licensing Examiner (since November 2020)
Department of Commerce, Community & Economic Development
Division of Corporations, Business and Professional Licensing
Post Office Box 110806
Juneau, Alaska 99811-0806
(907) 465-2550

Board of Pharmacy
FY 2021 Annual Report

Narrative Statement

The Alaska Board of Pharmacy "the board" endeavors to promote, preserve, and protect the public health, safety, and welfare of the public by and through the effective control and regulation of the practice of pharmacy. During FY2021, the board continued its efforts to support the pharmaceutical supply chain, marking one year of expanding its regulatory oversight of non-resident wholesale drug distributors, outsourcing facilities, and third-party logistics providers. The board of pharmacy continued to regulate in-state pharmacies, out-of-state pharmacies, remote pharmacies, drug rooms, in-state wholesale drug distributors, pharmacists, pharmacist interns, and pharmacy technicians. In all, the board added over 1,250 new licensees to its user base in FY2021, bringing the total number of regulated individuals and entities to approximately 4,700. The board also continued to regulate shared pharmacy services and telepharmacy systems, review and approve collaborative practice agreements with practitioners, and administer the state's controlled substance prescription database, the Prescription Drug Monitoring Program (PDMP).

Through its comprehensive emergency response, the board continued to support the state's strategic health response, balance healthcare delivery sites, and aid in the scaling up of vital pharmacy support services during this unprecedented pandemic. The board swiftly implemented emergency preparedness regulations in FY2020, making these permanent in July FY2021. These regulations reduce barriers to licensure and bridge accessibility gaps to critical patient services by relaxing license application requirements and allowing for the delivery of medications by support staff without the need to obtain licensure. By mid-FY2021, the board expanded its existing emergency pharmacist permit to include pharmacist interns and pharmacy technicians, expediting priority license applications and increasing pharmacy personnel coverage across the state. The board also created a new courtesy license category to allow pharmacy personnel to provide COVID-19 vaccines. These collective efforts, which align with the U.S. Department of Health and Human Services' (HHS) Public Readiness and Emergency Preparedness Act (PREP Act) – helped to elevate the state's vaccine distribution capacity and alleviate immunization strains bottlenecked by previous limitations on certain personnel authorized to provide this service..

Legislatively, the board testified in support of the Alaska Pharmacists Association's (AKPhA) pharmacist mobilization bill, HB145, which highlights the reality that pharmacists are uniquely positioned and qualified to assist with the scaling up of patient care and in filling critical health management gaps. The bill introduced language to recognize pharmacists as providers for the purpose of meeting insurance reimbursement eligibility and to clarify that prescribing for general wellness is already within pharmacists' scope of practice, particularly for those working in institutional and primary care settings. Additionally, the board supported the Nurse Licensure Compact bill and took a neutral position on the Board of Veterinary Examiner's PDMP exemption bill.

The board is statutorily required to meet at least three (3) times per year either in person or telephonically. In FY2021, the board held five (5) regular board meetings via video conference, realizing a $$$ savings than if the meetings were held in person. Through regulatory subcommittees, the board continued its efforts to reduce regulatory barriers, identify outdated regulations, and assess for administrative efficiencies. In its ongoing effort to adhere to its mission, the board also approved its 2021 Strategic Plan, which includes goals and strategies around the areas of communication, administration, licensure, and regulation and enforcement.

The Board of Pharmacy also maintains its membership with the National Association of Boards of Pharmacy (NABP) and the National Association of Controlled Substance Authorities (NASCA), which provides the board with industry support and access to national resources, many of which provides administrative efficiency and supports the board in avoiding redundant services and lowering costs to the State, prospective applicants, and licensees. Through its membership with the NABP and at no additional cost, the board of pharmacy is able to delegate administration of its state jurisprudence exam for pharmacist licensure and reporting of disciplinary actions to the association. The NABP also provides an ePortal service for transfer of national examination scores and state licenses, a continuing education monitoring service, and intrastate and interstate datasharing hubs to facilitate exchange of data through the PDMP. Through its membership with NASCA, the board has access to discussion forums and comprehensive state information to assist in curtailing the abuse, misuse, and diversion of controlled substances

Board of Pharmacy
Fiscal Year 2021 Annual Report

Budget Recommendations for FY 2022

The Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff
☐ Airfare:			$0.00
☐ Hotel:			$0.00
☐ Ground:			$0.00
☐ Other:			$0.00
Total Estimated Cost:			**$0.00**

Board Meeting Date	Location	# Board	# Staff
☐ Airfare:			$0.00
☐ Hotel:			$0.00
☐ Ground:			$0.00
☐ Other:			$0.00
Total Estimated Cost:			**$0.00**

Board Meeting Date	Location	# Board	# Staff
☐ Airfare:			$0.00
☐ Hotel:			$0.00
☐ Ground:			$0.00
☐ Other:			$0.00
Total Estimated Cost:			**$0.00**

Board of Pharmacy
Fiscal Year 2021 Annual Report

Budget Recommendations for FY 2022

The Budget Recommendations section anticipates the board's fiscal priorities for the upcoming year. Please complete all parts of this section with details about anticipated meetings, conferences, memberships, supplies, equipment, to other board requests. Meeting expenses that are being funded through third-party reimbursement or direct booking must be identified separately from expenses paid through license fees (receipt-supported services or RSS). Be sure to explain any items listed as "other" so they may be tracked appropriately.

Board Meeting Date	Location	# Board	# Staff

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Other:	$0.00
Total Estimated Cost:	**$0.00**

Board Meeting Date	Location	# Board	# Staff

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Other:	$0.00
Total Estimated Cost:	**$0.00**

Board Meeting Date	Location	# Board	# Staff

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Other:	$0.00
Total Estimated Cost:	**$0.00**

Budget Recommendations for FY 2022 (continued)

Travel Required to Perform Examinations

☐ Not applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

☐ Airfare:	$0.00
☐ Hotel:	$0.00
☐ Ground:	$0.00
☐ Conference:	$0.00
☐ Other:	$0.00
Describe "Other" (break out all sections):	
Total Estimated Cost:	**$0.00**

Out-of-State Meetings and Additional In-State Travel (Rank in order of importance)

☐ #1 Rank in Importance or ☐ Not Applicable

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#2 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#3 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#4 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#5 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#6 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Out-of-State Meetings and Additional In-State Travel

#7 Rank in Importance

Date	Location	# Board	# Staff

Description of meeting and its role in supporting the mission of the Board:

Expenditure	License Fees (RSS)	Third-Party Reimbursement	Third-Party Direct Booked	Total
☐ Airfare:	$0.00	$0.00	$0.00	$0.00
☐ Hotel:	$0.00	$0.00	$0.00	$0.00
☐ Ground:	$0.00	$0.00	$0.00	$0.00
☐ Conference:	$0.00	$0.00	$0.00	$0.00
☐ Other	$0.00	$0.00	$0.00	$0.00
Describe "Other" (break out all sections):				
Net Total:	**$0.00**	**$0.00**	**$0.00**	**$0.00**

Budget Recommendations for FY 2022 (continued)

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

Non-Travel Budget Requests

☐ Not Applicable ☐ Resources ☐ Examinations
☐ Membership ☐ Training ☐ Other

Product or Service	Provider	Cost Per Event
		$0.00

Description of item and its role in supporting the mission of the Board:

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Budget Recommendations for FY 2022 (continued)

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event: **$0.00**
Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event: **$0.00**
Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

☐ **Not Applicable**

Cost Per Event: **$0.00**
Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Budget Recommendations for FY 2022 (continued)

Other Items with a Fiscal Impact

Cost Per Event: **$0.00**

☐ **Not Applicable**

Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Other Items with a Fiscal Impact

Cost Per Event: **$0.00**

☐ **Not Applicable**

Number of Events: **0**

Product or Service	Provider	Total Cost
		$0.00

Description of item and its role in supporting the mission of the Board:

Summary of FY 2022 Fiscal Requests

Board Meetings and Teleconferences:	$0.00
Travel for Exams:	$0.00
Out-of-State and Additional In-State Travel:	$0.00
Dues, Memberships, Resources, Training:	$0.00
Total Potential Third-Party Offsets:	–$0.00
Other:	$0.00
Total Requested:	**$0.00**

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Legislation Recommendations Proposed Legislation for FY 2022

☐ **No Recommendations**
The Board has no recommendations for proposed legislation at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed legislation:

The Alaska Pharmacists Association (AKPhA) introduced legislative changes through HB 145 in FY2021 that overlap with changes the Board of Pharmacy previously identified in its FY2020 legislative recommendations, including:

- Removing "dosage form" from the definition of "equivalent drug product" in AS 08.80.480.
- Clarifying pharmacists' ability to independently prescribe and administer vaccines and emergency medications under AS 08.80.168, and expand their ability to provide independent treatment to other conditions as appropriate
- Allowing pharmacist interns and pharmacy technicians, as supervised by a pharmacist, to prescribe vaccines and emergency medications under AS 08.80.168, and expand their ability to provide supervised treatment to other conditions as appropriate
- Allowing other pharmacy personnel, as delegated by the pharmacist, to disclose prescription prices, including less costly alternatives per AS 08.80.297

A summary of the Board of Pharmacy's legislative recommendations include:

Statutory area	Summary of Change	Citation
Annual report	Remove annual report requirement; no longer require out-of-state pharmacies to report changes to the board annually; allow updates to be provided at the time of renewal	AS 80.80.158(b)
Moral character	Remove moral character requirement from applications for pharmacists via examination, reciprocity,	AS 08.80.110(2), AS 08.80.145(3)
Registration of pharmacies	Repeal registration and introduce licensure category	AS 08.80.158
Requirements for non-resident pharmacies	Include devices, require licensure	AS 08.80.159
Licenses not affected	Drug dispensing machines	AS 08.80.400
Prohibited terms	Add "apothecary"	AS 08.80.420

Legislation Recommendations Proposed Legislation for FY 2022 *(Continued)*

The Board of Pharmacy's proposed changes are as follows:

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall
(1) be fluent in the reading, writing, and speaking of the English language;
~~(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;~~
(3) be a graduate of a college in a degree program approved by the board;
(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;
(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person
~~(1)~~ submits a written application to the board on a form required by the board;
(2) is at least 18 years of age;
~~(3) is of good moral character;~~
(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;
(5) has engaged in the practice of pharmacy for at least one year ~~or has met the internship requirements of this state~~ within the one-year period immediately before applying for a license under this section;
(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;
(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and (8) pays all required fees.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:
(1) examination;
(2) reexamination;
(3) investigation for licensing by license transfer; (4) pharmacist license;
(5) temporary license;
(6) pharmacy technician license;
(7) pharmacy intern license;
(8) emergency permit;
(9) license amendment or replacement;
(10) ~~registration or~~ licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.168. PRESCRIBE AND ADMINISTER ~~ADMINISTRATION OF~~ DRUGS ~~VACCINES AND RELATED EMERGENCY~~ ~~MEDICATIONS.~~
(a) A pharmacist may independently prescribe
(1) and administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(2) and dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).
(3) and dispense dietary fluoride supplements when prescribed according to the American dental association's recommendations for persons whose drinking water is proven to have a fluoride content below the United States department of health and human services' recommended concentration;
(4) and dispense epinephrine auto-injectors;
(5) and dispense drugs, drug categories, or devices that are prescribed in accordance with the product's federal food and drug administration-approved labeling and that are limited to conditions that:
(A) do not require a new diagnosis;
(B) are minor and generally self-limiting;
(C) have a test that is used to guide diagnosis or clinical decision-making and are waived under the federal clinical laboratory improvement amendments of 1988; or
(D) in the professional judgment of the pharmacist, threaten the health or safety of the patient should the prescription not be immediately dispensed. In such cases, only sufficient quantity may be provided until the patient is able to be seen by another provider.
(6) In this section,
(1) "opioid overdose drug" has the meaning given in AS 17.20.085;
(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

(b) The board shall not adopt any regulations authorizing a pharmacist to prescribe a controlled drug, compounded drug or biological product.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. (a) This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant, advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.
(b) This section does not apply to the placement of automated prescription drug dispensing machines. Prescription drug dispensing machines, outside of institutional facilities, that are intended to regularly dispense drugs to patients shall be licensed by the board.
(c) In this section, "regularly" means to dispense more than a 3-day supply to a patient.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," "apothecary", or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Board of Pharmacy
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Regulation Recommendations Proposed Legislation for FY 2022

☐ **No Recommendations**
The Board has no recommendations for proposed regulations at this time.

☒ **Recommendations**
The Board has the following recommendations for proposed regulations:

12 AAC 52.020. ~~FACILITY~~ PHARMACY LICENSE. (repeal & readopt)

(a) An applicant for a ~~facility~~ **pharmacy** license shall submit
(1) the **applicable** fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) **an attestation that** within 14 days after commencement of business, a ~~completed~~ self-inspection ~~of the premises questionnaire~~ on a form provided by the department **will be completed**. **The self-inspection must be retained, and available upon request, for the duration of the licensing period in which it was completed;** and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.
(f) a pharmacy that has changed its name, ownership, or physical address shall apply for a new and separate license in accordance with this section.

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (repeal)

(a) ~~The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall~~
~~(1) submit a new, completed application for a pharmacy license on a form provided by the department; and~~
~~(2) pay the duplicate license fees required in 12 AAC 02.105;~~
~~(3) repealed 1/17/2007.~~
~~(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.~~

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (repeal)

~~(a) Repealed 1/17/2007.~~
~~(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.~~

Regulation Recommendations Proposed Legislation for FY 2022 *(Continued)*

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (amend)

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

~~**(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or**~~

(B) a ~~**certified**~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~**and**~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080 ~~**from the agency where the hours of internship or experience were completed**~~;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (amend)

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(2) pays the ~~**application fee and the out-of-state pharmacy registration**~~ **applicable** fee**s** established in 12 AAC 02.310;

(3) submits a ~~**certified true**~~ copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an **attestation that an** inspection report or self-inspection report **was** completed within the last two years **or since the last time the registration was initially issued. A self-inspection must be retained, and made available upon request, for the duration of the licensing period in which it was completed.**

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (amend)

~~(a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.~~

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;
(2) the applicable fees established in 12 AAC 02.310;
(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;
(4) either

~~(~~**~~(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or~~**

(B) a ~~**certified**~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~**and**~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (amend)

~~(a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements set out in (c) of this section has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity.~~
~~(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.~~
(c) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;
(2) the applicable fees established in 12 AAC 02.310;
(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;
(4) either

~~**(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or**~~

(B) a ~~**certified**~~ copy of

(i) the original pharmacy school diploma issued to the applicant **from a college of pharmacy accredited by the ACPE**; ~~and~~ **or**

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;
(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080.~~**; the verification must be sent directly to the department from the agency where the hours of internship or**~~

Board of Pharmacy
Fiscal Year 2021 Annual Report

Goals and Objectives

Part I

FY 2021's goals and objectives, and how they were met:

The Board of Pharmacy identified fourteen (14) goals for FY2021, most of which have been met or are ongoing efforts to be incorporated into the board' strategic plan. Included in this section are the board's strengths, weaknesses, opportunities, and threats (SWOT), to illustrate its assets, capabilities, and internal and external challenges for both the aspects of licensing and the Prescription Drug Monitoring Program (PDMP).

SWOT 1. Pharmacy Licensing

Strengths	Weaknesses	Opportunities	Threats
•Complete board membership •Technologically adaptive •Responsive staff •Use of diverse communication channels •Established licensing policies and procedures •Special topic subcommittee meetings •Emergency preparedness regulations •Task list accountability and follow-up •Rapport with stakeholders (AKPhA, DHSS)	•Staff turnover	•Expedited online licensing through myAlaska •Expanded public comment opportunities	•Closure of services applicants need to complete licensure (exam services, inspectors, fingerprints) during COVID-19 •Shifting priorities due to COVID-19

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

SWOT 2. Prescription Drug Monitoring Program (PDMP)

Strengths	Weaknesses	Opportunities	Threats
•BOP established process to use as model by other boards: screening of requirements incorporated into applications; tracking of mandatory use compliance through designations; concurrent processing of PDMP registration and license renewals •Training documents and videos •Comprehensive website content and FAQs •Quarterly statistics reports provided to boards •Database enhancement features to display risk-based patient alerts	•Lack of receipt authority •Technological limitations •Personnel shortage •Differing priorities and processes amongst licensing boards	•PDMP Board Chairs meetings •Education and outreach •Awareness and feedback questionnaire •Collaboration with stakeholders (IHS, VA, military, HIE, DHSS, professional associations) •Grant applications •Development of disciplinary matrices	•Inconsistent funding opportunities •low compliance due to time constraints and technological integration gaps •Perceived relevance of PDMP to opioid crisis •Perceived lack of enforcement for non-compliance

Goal #1: The board will continue to promote, preserve, and protect the public, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Status: met by

1.) Regulation of pharmacists, pharmacist interns, pharmacy technicians, pharmacies, drug rooms, wholesale drug distributors, outsourcing facilities, and third-party logistics providers
2.) Review and approval of collaborative practice agreements
3.) Administration of the Prescription Drug Monitoring Program (PDMP)
4.) Promulgation of regulations related to emergency preparedness
5.) Issuing guidance to pharmacy personnel in response to the COVID-19 pandemic

Goal #2: The board will continue to provide input and comment on any proposed regulations involving medications, pharmaceutical care, or the practice of pharmacy.

Goals and Objectives (continued)

Status: The board was not aware of new opportunities to provide comment on proposed regulations.

Goal #3: The board will continue to promote effective patient counseling by licensees.

Status: The board continues to promulgate regulations for mandatory patient counseling under 12 AAC 52.585. Additionally, the board amended 12 AAC 52.992(d) allowing a pharmacist intern to offer vaccine information statements (VIS) to patients. The board replaced *provide*, with *offer*, which improves patient engagement and encourages dialogue around these preventative services.

Goal #4: The board will continue to assess and evaluate the multi-state pharmacy jurisprudence examination (MPJE) and send two members to the MPJE Item Development workshop.

Status: This was not met due to threats; see SWOT 1.

Goal #5: The board will continue to assess and evaluate the licensing of pharmacy technicians and discuss the introduction, recognition, and duties for a nationally certified pharmacy technician.

Status: on March 27, 2020 the board adopted emergency regulations, including recognition of pharmacy technicians with national certifications. The emergency regulations took effect on April 3, 2020 and were adopted as permanent on May 28, 2020, the Board of Pharmacy adopted the emergency regulation changes to be made permanent. The permanent emergency regulation changes were approved, signed, and filed by the Lieutenant Governor on July 31, 2020.

Goal #6: The board will continue to assess and evaluate the jurisprudence practice exam and its effectiveness as a learning tool for interns.

Status: the jurisprudence exam is still required for initial intern licensure. In the board's emergency preparedness regulations, repealed on April 3, 2020 and made permanent on July 31, 2020, the board removed the jurisprudence exam requirement for renewal of pharmacist and pharmacy technician licensure.

Goal # 7: The board will continue its affiliation with the National Association of Boards of Pharmacy (NABP) and send one member to the District 7 NABP meeting and two members to the annual NABP meeting.

Status: Dr. Ruffridge attended the District 7 NABP meeting held virtually on October 13, 2020. Following participation at this meeting, Dr. Ruffridge shared the district's resolutions with the Board of Pharmacy, which discussed the matter of a "just culture" regulatory approach during their December 3-4, 2020. Laura Carrillo and Justin Ruffridge attended the annual NABP meeting held virtually on May 13-14, 2021.

Goal #8: The board will continue to evaluate the impact of current regulations and the need for new regulations or amendments to current regulations to advance our mission.

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

Status: In drafting emergency preparedness regulations, and with the intent to make these changes permanent, the board also took this as an opportunity to assess changes to regulatory areas for improving patient care and expanding pharmacy services without jeopardizing the board's responsibility of effective oversight. These changes were made:

- Increasing service capacity by expanding the tasks for which a pharmacy technician with a national certification may perform, including performing final checks on non-controlled substances and clarify or obtain missing information on a prescription order
- Maximizing available pharmacy personnel resources by allowing a cashier or bookkeeper to work in a pharmacy without being licensed as a technician
- Expanding pharmacy intern capabilities, including transferring and performing final checks on prescription drug orders, marking the quantity and date of refills, dispensing electronically transmitted prescriptions, and dispensing substitutions if authorized by the practitioner
- Decreasing unnecessary administrative requirements, including reducing documentation review for items replaced by applicant and licensee attestations
- Improving continuation of patient care by removing the 30-day supply limitation and allowing a pharmacist or pharmacist intern to dispense any quantity of a prescription order for non-controlled substances
- Expanding shared pharmacy services to include pharmacist interns, pharmacy technicians with national certification, and allowing for counseling and monitoring of drug therapy through these services

Goal #9: The board will continue to assess and evaluate the growing public concern regarding the abuse of illicit and prescription drugs, internet pharmacies, counterfeit drugs and support continuing funding and enhancement for the PDMP.

Status: The board continues to administer the PDMP for all six affected healthcare boards and manages deliverables from three separate federal grants. The board initiated a PDMP Board Chairs committee in October 2020, which meets bi-weekly to discuss challenges and solutions to registration and use. Through its PDMP manager, the board provides quarterly statistics reports to prescribing boards on metrics concerning dangerous combinations of therapy, high MME prescribing, and registration and review compliance. The Board of Pharmacy established its own disciplinary guidelines for failure to register and failure to report, which are monitored an on-going and quarterly basis, respectively. See SWOT 2.

Goal #10: The board will monitor, assess, evaluate, and modify the Alaska PDMP based on the best interest of the public and profession.

Status: the board launched an Awareness and Feedback questionnaire from _____ to ____ to gauge user interaction and compliance, and to assess regulatory and technological gaps to access, visibility, and use. In an effort to standardize registration timeframes and increase timely access to the system, the board proposed a 30-day registration timeframe, which became effective May 6 of FY2021.

Goals and Objectives (continued)

Part I (continued)

FY 2021's goals and objectives, and how they were met:

Goal #11: The board will develop a strategic plan around communication, administration, regulation and legislation, licensure, and enforcement.

Status: The board reviewed and approved its 2021 strategic plan in May 2021 and will review and approve their 2022 strategic plan in September 2021.

Goal #12: The board will continue its affiliation and collaboration with the Alaska Pharmacists Association, including attendance at its annual meetings.

Status: On February 14, 2021, Dr. Ruffridge presented to the AKPhA a summary of the board's regulatory changes in 2020. PDMP Manager, Lisa Sherrell, also provided an overview presentation of the database and aggregate statistics.

Goal #13: The board will support its staff in participating at training opportunities and attendance at professional conferences, including training to support assigned investigators.

Status: Staff participated in training opportunities and conferences virtually as permissible, including the NABP District 7 Meeting (October 13, 2020), CLEAR Investigator Training (October 19 – November 2, 2020), Pain Clinic Closure Workshop (January 12 and 14, 2021), National Drug Abuse and Heroin Summit (April 5-8, 2021), and Annual NABP Meeting (May 13-14, 2021).

Goal #14: The board will continue to simply its statutes and regulations by assessing outdated, burdensome, or unnecessary regulations.

Status: the board's right-touch regulations subcommittee met on November 18, 2020 to discuss potential redundant and/or obsolete regulations. As a result of this subcommittee meeting, the board requested guidance from the DOL around the definition of "practice of pharmacy" and limitations around the independent administration of drugs. The DOL introduced the concept of Negative Implication Canon, which is used in legal drafting and states that the explicit mention of certain topics excludes other topics not clearly mentioned. This term was brought forward to support the HB 145 and to articulate that because statute calls out independent administration of vaccines and emergency medications, it prohibits pharmacists from the independent administrative of other therapies. The board will continue to pursue right-touch regulations in FY2021, including but not limited to the following areas:

- Simplifying pharmacy licensure, including replacing the inspection report requirement with an attestation
- Simplifying pharmacist licensure, including repealing the transcripts requirement
- Simplifying pharmacist intern licensure, including repealing the jurisprudence questionnaire
- Clarifying procedures for facilities when a change of address, ownership, name, or manager has occurred
-

Board of Pharmacy
Fiscal Year 2021 Annual Report

Goals and Objectives

Part II

FY 2022's goals and objectives, and proposed methods to achieve them. Describe any strengths, weaknesses, opportunities, threats and required resources:

Below is the Board of Pharmacy's 2021 strategic plan, which includes its priority goals and strategies. The board intends to continue pursuing these goals in FY2022.

ALASKA BOARD OF PHARMACY
2021 STRATEGIC PLAN

The Alaska Board of Pharmacy endeavors to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

GUIDING PRINCIPLES	GOALS	STRATEGIES
COMMUNICATION	**1.** Engage in effective communication and promote transparency of public information.	**1.1** Improve customer service by providing timely updates to applicants and licensees. **1.2** Encourage appropriate disclosure of information related to licensing and investigative processes. **1.3** Maximize communication channels through the Board of Pharmacy website and List Service. **1.4** Increase collaboration with health care licensing boards and key stakeholders to address important health issues.
ADMINISTRATION	**2.** Adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.	**2.1** Avoid delays in application processing by maintaining adequate staffing and exploring retention strategies. **2.2** Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process. **2.3** Automate licensure through online applications. **2.4** Exercise fiscal discipline through effective budget management.
LICENSURE	**3.** Ensure competency and qualifications prior to licensure and renewal.	**3.1** Adhere to established licensing standards by reviewing education, experience, and examination requirements. **3.2** Periodically review applications and forms for alignment with existing requirements.
REGULATION & ENFORCEMENT	**4.** Grow the economy while promoting community health and safety.	**4.1** Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety. **4.2** Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP). **4.3** Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance. **4.4** Establish disciplinary guidelines and conduct random audits to ensure safety protocols and competencies are met. **4.5** Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arises.

For more information, please visit the following resources:

Board of Pharmacy Homepage: pharmacy.alaska.gov
Prescription Drug Monitoring Program (PDMP): pdmp.alaska.gov

Email: pharmacy@alaska.gov
Phone: 907-465-1073

Goals and Objectives (continued)

Part II (continued)

FY 2022's goals and objectives, and proposed methods to achieve them. Describe any strengths, weaknesses, opportunities, threats and required resources:

Goal #1: engage in effective communication and promote transparency of public information.

Strategy 1.1: Improve customer service by providing timely updates to applicants and licensees.
Strategy 1.2: Encourage appropriate disclosure of information related to licensing and investigative processes.
Strategy 1.3: Maximize communication channels through the Board of Pharmacy website and List Service.
Strategy 1.4: Increase collaboration with health care licensing boards and key stakeholders to address important health issues.

Goal #2: adhere to and strive for improved organizational efficiencies without compromising quality of record keeping.

Strategy 2.1: Avoid delays in application processing by maintaining adequate staffing and exploring retention strategies.
Strategy 2.2: Maintain a proactive approach to licensing by consulting historical knowledge, researching national trends, and encouraging innovation in the planning process.
Strategy 2.3: Automate licensure through online applications.
Strategy 2.4: Exercise fiscal discipline through effective budget management.

Goal #3: Ensure competency and qualifications prior to licensure and renewal.

Strategy 3.1: Adhere to established licensing standards by reviewing education, experience, and examination requirements.
Strategy 3.2: Periodically review applications and forms for alignment with existing requirements.

Goal #4: Grow the economy while promoting community health and safety.

Strategy 4.1: Routinely review effectiveness of regulations that reduce barriers to licensure without compromising patient health and safety.
Strategy 4.2: 4.2Combat the opioid crisis by effective administration of the state's Prescription Drug Monitoring Program (PDMP).
Strategy 4.3: Reduce adverse health outcomes during emergencies through prompt regulatory responses and board guidance.
Strategy 4.4: Establish disciplinary guidelines and conduct random audits to ensure safety protocols and competencies are met.
Strategy 4.5: 4.5Advocate for legislation as the pharmacy profession evolves and new opportunities for improved patient safety arises.

Goals and Objectives (continued)

Part II (continued)

FY 2022's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

Goals and Objectives (continued)

Part II (continued)

FY 2022's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

Goals and Objectives (continued)

Part II (continued)

FY 2022's goals and objectives, and proposed methods to achieve them.
Describe any strengths, weaknesses, opportunities, threats and required resources:

Board of Pharmacy
Fiscal Year 2021 Annual Report

Sunset Audit Recommendations

Date of Last Legislative Audit:
Board Sunset Date:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Sunset Audit Recommendations (continued)

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Sunset Audit Recommendations (continued)

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

Audit Recommendation:
Action Taken:
Next Steps:
Date Completed:

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, & Economic Development

Corporations, Business, & Professional Licensing
Board of Pharmacy

P.O. Box 110806
Juneau, Alaska 99811-0806
Main: 907.465.2550
Fax: 907.465.2974

November 17, 2020

To Board of Nursing

Through this letter, the Board of Pharmacy is requesting the Board of Nursing to consider repealing its regulation, 12 AAC 42.440(c)(2) which states:

> *(c) Authorized prescriptions by an APRN must*
> *(1) comply with all applicable state and federal laws; and*
> *(2) contain the signature of the prescriber followed by the initials "APRN" and the prescriber's identification number assigned by the board.*

Subsection (c)(2) raises several opportunities, and we are thus respectfully asking if the Board of Nursing would consider repealing subsection (c)(2). There are significant opportunities associated with this subsection, including:

1) How is this monitored and enforced?
    a. In its current form, pharmacists would need to be aware of this prescription requirement, which is not in our regulations, and act as the enforcement mechanism.
2) What does a pharmacist do if the APRN does not include this information after their signature?
    a. Is the prescription to be refused because it is not valid per this regulation?
    b. Is the pharmacist to call the practitioner?
        i. What happens if the pharmacist cannot reach the practitioner?
        ii. Are they authorized to add it? With or without approval?
    c. Does the prescription need to be returned to the practitioner?
3) Pharmacies are audited by third-party insurance companies to ensure prescriptions adhere to state and federal regulations.
    a. If a prescription is discovered that is not in compliance with regulation, they seek recoupment from the pharmacy because it doesn't meet the regulatory requirements.
    b. If a filled prescription under this scenario is found to be missing this information, then this could create complications for the pharmacy with the third-party entity.

Thank you for your professional partnership and consideration in repealing 12 AAC 42.440(c)(2).

Richard Holt, PharmD, MBA
Chair, Alaska Board of Pharmacy

CORRESPONDENCE

From: Schaber, Ashley R
To: Carrillo, Laura N (CED); "dokholt@mac.com"
Cc: Gray, Molly; gglaspy@bartletthospital.org
Subject: Topic for May Board of Pharmacy Meeting
Date: Wednesday, April 21, 2021 11:37:20 AM

Good morning Laura and Rich,
I wanted to request that the Board of Pharmacy discuss the topic of white bagging at the upcoming meeting in May. White bagging is dispensing infusion drugs, typically the high-cost drugs, via a patient's pharmacy benefit through a designated specialty pharmacy. The drug is then shipped to the infusion pharmacy to be given to the patient. The site infusing the medication is not able to bill for the drug although nursing can bill an administration fee. From a pharmacy standpoint, there are concerns with the supply chain and storage. This has become a really hot topic at multiple sites providing infusions in our state, impacting patient care.

I have been asked to reach out on this topic on behalf of Alaska Native Medical Center. In further discussions have found this is a pretty wide-spread issue throughout AK, so AKPhA is working on an official recommendation to the Board of Pharmacy. We will be compiling more detailed information in the next week or so, but I wanted to go ahead and get this on the agenda.

Respectfully,
Ashley Schaber

Ashley Schaber, Pharm.D., MBA, BCPS
CDR, United States Public Health Service
Alaska Native Medical Center
Inpatient Pharmacy Manager
4315 Diplomacy Drive
Anchorage, Alaska 99508
Phone: (907)729-2154
arschaber@anthc.org

From: IGA
To: Adams, Michelle
Subject: FDA Continues Important Steps to Ensure Quality, Safety and Effectiveness of Authorized COVID-19 Vaccines
Date: Wednesday, April 21, 2021 5:40:54 AM
Attachments: image002.png

Hello,

The FDA Intergovernmental Affairs team would like to bring to your attention the following FDA Statement - **FDA Continues Important Steps to Ensure Quality, Safety and Effectiveness of Authorized COVID-19 Vaccines.**

FDA Continues Important Steps to Ensure Quality, Safety and Effectiveness of Authorized COVID-19 Vaccines

The following statement is attributed to
Acting FDA Commissioner Janet Woodcock, M.D., and
Peter Marks, M.D., Ph.D., director of the FDA's Center for Biologics Evaluation and Research

The U.S. Food and Drug Administration takes its responsibility to ensure medical product quality, safety and effectiveness very seriously. The American public puts its trust in the agency to ensure that all medical products, including COVID-19 vaccines, meet the agency's standards for quality, safety and effectiveness.

As part of our regulatory processes for reviewing all manufacturing facilities, the FDA recently completed an inspection of Emergent BioSolutions, a proposed manufacturing facility for the Johnson & Johnson COVID-19 Vaccine. As Johnson & Johnson announced last month, the FDA has not authorized this facility to manufacture or distribute any of Johnson & Johnson's COVID-19 Vaccine or components and, to date, no COVID-19 vaccine manufactured at this plant has been distributed for use in the U.S.

The FDA's inspections are thorough, and these assessments review the quality of manufacturing procedures, including records, staff training, facility operations, drug production and testing and the systems in place to ensure product quality. During an inspection of Emergent BioSolutions that ended Tuesday, the FDA cited a number of observations concerning whether the facility's processes met our requirements and standards. These observations are outlined in our inspection closeout report, also known as a "FDA Form 483."

The FDA's observations are intended to identify certain conditions observed during an inspection that have the potential to lead to quality issues during the manufacturing of a product. Once we observe such conditions, we can then work with a company to help identify a path forward to remedy the issues.

Indeed, it is often in the public's best interest that the FDA work with firms to quickly resolve compliance matters to ensure that the public has access to medical products that meet the agency's high standards for quality, safety and effectiveness.

In the case of Emergent BioSolutions, we are working with the company to address the conditions identified. At the agency's request, Emergent BioSolutions has agreed to pause new production while it works with the FDA to resolve potential quality issues. For the vaccines already manufactured, the products will undergo additional testing and will be thoroughly evaluated to ensure their quality before any potential distribution. We will not allow the release of any product until we feel confident that it meets our expectations for quality.

These actions are unrelated to an ongoing evaluation by the FDA and U.S. Centers for Disease Control and Prevention of extremely rare cases of a specific type of blood clot reported in a very small number of individuals after receiving the Johnson & Johnson COVID-19 Vaccine.

We are doing everything we can to ensure that the COVID-19 vaccines that are given to the people of this nation have met the agency's high standards for quality, safety and effectiveness. We know that every time an American, including members of our own families, receives a COVID-19 vaccine dose, they are putting their trust in us. We are working hard to maintain that trust.

Related Information

- Emergent BioSolutions 483
- FDA Form 483 Frequently Asked Questions
- FDA COVID-19 Vaccines

You can find the FDA Statement on our website here. We hope this information is helpful. Please feel free to contact me or FDA's IGA staff at IGA@fda.hhs.gov if you have any questions. Thank you.

Regards,
Michelle

Michelle Adams, MPH
Senior Intergovernmental Affairs Specialist
Intergovernmental Affairs (IGA)
Office of the Commissioner/OPLIA
U.S. Food and Drug Administration
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Subscribe to FDA email notifications here
FDA website for Federal, State, Local, Tribal, and Territorial Officials here

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Eileen Lewalski, Professional Affairs Senior Manager

DATE: April 15, 2021

RE: *Model Act* Review Committee

As you may know, the *Model State Pharmacy Act and the Model Rules of the National Association of Boards of Pharmacy (Model Act)* provides the boards of pharmacy with model language that may be used when developing state laws or board rules. The *Model Act* includes sections for and expert legal commentary on boards of pharmacy, licensing (pharmacists, technicians, and facilities), and discipline. The *Model Act* currently is updated each August pursuant to the suggested amendments from the following.

- Member input from resolutions
- Task forces
- Executive Committee recommendations
- Newly enacted or amended federal laws, regulations, and guidances
- Committee on Law Enforcement/Legislation (LE/L) review of the above

The Association is excited to inform you that the NABP Executive Committee (EC) has approved the formation of an expert committee that will periodically conduct a thorough review of the *Model Act* to ensure the following are updated for relevance and accuracy.

- Dates
- Footnotes
- References to federal law and regulations and standard setting organizations, such as United States Pharmacopeial Convention and Accreditation Council for Pharmacy Education
- Overall language to shift to a standard of care and remove outdated prescriptive provisions

Beginning in 2021, this review will take place every five years during the third quarter, and the results will be compiled and provided to LE/L, which meets every January. The *Model Act* Expert Committee will be appointed by the NABP president and will be comprised of eight individuals who are pharmacists and/or attorneys who possess a deep understanding of federal and state laws, regulations, and guidances, as well as standard setting organizations. At least one member must be a board executive director. Of the members, a chair will be appointed, and a member of the EC will be chosen to serve as the EC Liaison.

Committee members will be provided with a copy of the *Model Act* and assigned a section to review remotely over a four-week period. NABP staff will hold an introductory one-hour call with the Committee to go over the review process, a second half-day call at the two week point to discuss progress and findings, then a conclusory half-day call will be held to review the final recommendations. As is the case with all task forces and committees, staff will compile the recommendations and provide the Committee with a report. Once finalized, that report will be presented to the EC for their review and approval.

As a reminder, executive officers and board members, including public members, interested in serving on a committee or task force are encouraged to submit a letter of interest and a current résumé or curriculum vitae. In addition, NABP encourages affiliated members from associate member boards and interested board of pharmacy staff to volunteer for NABP task forces. Letters should outline the volunteer's applicable experiences and accomplishments, along with the reasons he or she wishes to be considered for appointment to a committee or task force.

If you have yet to do so, all submissions must be sent to NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, at NABP Headquarters or ExecOffice@nabp.pharmacy, or via the NABP website, by **Friday, June 4, 2021.** All materials will be forwarded to NABP President-elect Caroline D. Juran, BSPharm, DPh (Hon), who will make the appointments when she becomes NABP President following the Association's 117th Annual Meeting, May 13-14, 2021.

cc: NABP Executive Committee
Lemrey "Al" Carter, Executive Director/Secretary

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: William “Bill” Cover, Associate Executive Director, State Pharmacy Affairs

DATE: April 20, 2021

RE: Outsourcing Facility Inspection/Accreditation Program Survey

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In December 2019, the NABP Executive Committee (EC) began assessing whether NABP should develop and offer a program that would involve the inspecting and/or accrediting of outsourcing facilities operating under section 503B of the Federal Food, Drug, and Cosmetic Act (Act).

At the committee’s request, NABP is seeking your feedback in determining how NABP can best support the needs of its members in the regulation of outsourcing facilities as it relates to compliance with Current Good Manufacturing Practices (CGMP).

NABP would appreciate your assistance by completing a survey via the link below. It should take only a few minutes to complete. Please respond to this brief survey by **Tuesday, May 4, 2021**. Thank you in advance for your attention and prompt response to this request.

Survey Link: https://www.surveymonkey.com/r/Z9VPD82

cc: NABP Executive Committee
Lemrey “Al” Carter, Executive Director/Secretary
Kevin McGlynn, Director, Accreditation and Inspection Programs
Gregg Jones, Compliance Senior Manager
Neal Watson, Member Relations and Government Affairs Senior Manager

NABP
National Association of Boards of Pharmacy

847/391-4406
Fax: 847/375-1114

1600 Feehanville Dr
Mount Prospect, IL 60056
help@nabp.pharmacy

TO: EXECUTIVE OFFICERS – STATE BOARDS OF PHARMACY

FROM: Lemrey “Al” Carter, Executive Director/Secretary

DATE: April 15, 2021

RE: Request for Information from Vermont

The Vermont Board of Pharmacy requested that NABP conduct a survey of the executive officers of state boards of pharmacy regarding pharmacy technician registration.

Please respond to the brief question below, along with the state board you represent, no later than Thursday, April 29, 2021. You may forward your responses to Carrie Phillips at Carrie.Phillips@vermont.gov, and copy NABP at ExecOffice@nabp.pharmacy.

- Does your state require pharmacy technicians that work for a 503B outsourcer to be registered as such?

Thank you for your assistance!

cc: NABP Executive Committee

BUDGET

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Board of Pharmacy	FY 14	FY 15	Biennium	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21 1st - 3rd QTR
Revenue											
Revenue from License Fees	$ 673,100	$ 269,646	$ 942,746	$ 802,230	$ 208,755	$ 1,010,985	$ 801,317	$ 213,770	$ 1,015,087	$ 631,105	$ 996,647
Allowable Third Party Reimbursements	1,701	-	1,701	-	3,256	3,256	210	962	1,172	$ -	$ -
TOTAL REVENUE	$ 674,801	$ 269,646	$ 944,447	$ 802,230	$ 212,011	$ 1,014,241	$ 801,527	$ 214,732	$ 1,016,259	$ 631,105	$ 996,647
Expenditures											
Non Investigation Expenditures											
1000 - Personal Services	132,988	115,222	248,210	156,115	151,947	308,062	204,727	194,745	399,472	199,334	203,289
2000 - Travel	24,054	24,548	48,602	16,676	11,119	27,795	13,704	8,299	22,003	2,641	-
3000 - Services	17,003	4,569	21,572	13,361	14,293	27,654	21,960	27,781	49,741	45,283	28,581
4000 - Commodities	69	90	159	111	519	630	-	26	26	521	-
5000 - Capital Outlay	-	-	-	-		-	-		-	-	-
Total Non-Investigation Expenditures	174,114	144,429	318,543	186,263	177,878	364,141	240,391	230,851	471,242	247,779	231,870
Investigation Expenditures											
1000-Personal Services	49,292	49,044	98,336	68,935	63,727	132,662	68,679	69,997	138,676	57,738	71,899
2000 - Travel								-	-	1,260	-
3023 - Expert Witness	-	-	-	-	2,800	2,800	-	-	-	-	-
3088 - Inter-Agency Legal	7,630	4,580	12,210	1,451	23,355	24,806	-	3,062	3,062	2,537	85
3094 - Inter-Agency Hearing/Mediation	-	-	-	-	883	883	-	-	-	694	152
3000 - Services other								400	400	269	13
4000 - Commodities								-	-	-	-
Total Investigation Expenditures	56,922	53,624	110,546	70,386	90,765	161,151	68,679	73,459	142,138	62,498	72,149
Total Direct Expenditures	231,036	198,053	429,089	256,649	268,643	525,292	309,070	304,310	613,380	310,277	304,019
Indirect Expenditures											
Internal Administrative Costs	123,716	72,555	196,271	128,025	123,008	251,033	150,986	155,128	306,114	164,443	123,332
Departmental Costs	45,898	48,021	93,919	48,707	73,682	122,389	78,139	81,374	159,513	58,131	43,598
Statewide Costs	28,298	25,287	53,585	15,564	26,226	41,790	30,555	27,069	57,624	33,868	25,401
Total Indirect Expenditures	197,912	145,863	343,775	192,296	222,916	415,212	259,680	263,571	523,251	256,442	192,331
									-		
TOTAL EXPENDITURES	**$ 428,948**	**$ 343,916**	**$ 772,864**	**$ 448,945**	**$ 491,559**	**$ 940,504**	**$ 568,750**	**$ 567,881**	**$ 1,136,631**	**$ 566,719**	**$ 496,350**
Cumulative Surplus (Deficit)											
Beginning Cumulative Surplus (Deficit)	$ 29,896	$ 275,749		$ 201,479	$ 554,764		$ 275,216	$ 507,993		$ 154,844	$ 219,230
Annual Increase/(Decrease)	245,853	(74,270)		353,285	(279,548)		232,777	(353,149)		64,386	500,297
Ending Cumulative Surplus (Deficit)	$ 275,749	$ 201,479		$ 554,764	$ 275,216		$ 507,993	154,844		219,230	719,527
Statistical Information											
Number of Licenses for Indirect calculation	4,134	4,756		4,649	5,068		5,680	6,203		5,934	

Additional information:

*• Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **

• Most recent fee change: Fee reduction FY20

• Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.

Appropriation Name (Ex)	(All)
Sub Unit	(All)
PL Task Code	PHA1

Sum of Budgetary Expenditures	**Object Type Name (Ex)**		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	145,282.36		145,282.36
1014 - Overtime	633.60		633.60
1023 - Leave Taken	24,365.14		24,365.14
1028 - Alaska Supplemental Benefit	10,409.78		10,409.78
1029 - Public Employee's Retirement System Defined Benefits	1,916.03		1,916.03
1030 - Public Employee's Retirement System Defined Contribution	8,539.69		8,539.69
1034 - Public Employee's Retirement System Defined Cont Health Reim	5,485.59		5,485.59
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	2,045.59		2,045.59
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	19,322.46		19,322.46
1039 - Unemployment Insurance	259.46		259.46
1040 - Group Health Insurance	46,325.64		46,325.64
1041 - Basic Life and Travel	68.44		68.44
1042 - Worker's Compensation Insurance	1,579.54		1,579.54
1047 - Leave Cash In Employer Charge	3,440.90		3,440.90
1048 - Terminal Leave Employer Charge	2,366.19		2,366.19
1053 - Medicare Tax	2,359.58		2,359.58
1063 - GGU Business Leave Bank Usage	-		-
1069 - SU Business Leave Bank Contributions	29.31		29.31
1077 - ASEA Legal Trust	191.02		191.02
1079 - ASEA Injury Leave Usage	19.46		19.46
1080 - SU Legal Trst	17.39		17.39
1970 - Personal Services Transfer	530.71		530.71
3000 - Training/Conferences		2,397.00	2,397.00
3035 - Long Distance		7.12	7.12
3045 - Postage		30.35	30.35
3046 - Advertising		1,144.53	1,144.53
3088 - Inter-Agency Legal		17,541.90	17,541.90
3094 - Inter-Agency Hearing/Mediation		151.90	151.90
3100 - Inter-Agency Safety		2,205.00	2,205.00
3085 - Inter-Agency Mail		5,352.99	5,352.99
Grand Total	**275,187.88**	**28,830.79**	**304,018.67**

Department of Commerce Community, and Economic Development
Corporations, Business and Professional Licensing

Summary of All Professional Licensing
Schedule of Revenues and Expenditures

Prescription Drug Monitoring Program	FY 14	FY 15	Biennium	FY 16	FY 17	Biennium	FY 18	FY 19	Biennium	FY 20	FY 21 1st - 3rd QTR
Revenue											
Revenue from License Fees	$ -	$ -	$ -			$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 166,915
Allowable Third Party Reimbursements	-	-	-	-	-	-	-	-	-	$ -	$ -
TOTAL REVENUE	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 90,765	$ 90,765	$ 26,150	$ 166,915
Expenditures											
Non Investigation Expenditures											
1000 - Personal Services			-			-	-	6,043	6,043	41,343	1,552
2000 - Travel			-			-	-	-	-	796	-
3000 - Services			-			-	-	11	11	6,155	1,162
4000 - Commodities			-			-	-	-	-	-	-
5000 - Capital Outlay	-	-	-	-		-	-		-	-	-
Total Non-Investigation Expenditures	-	-	-	-	-	-	-	6,054	6,054	48,294	2,714
Investigation Expenditures											
1000-Personal Services			-			-		-	-	-	-
2000 - Travel								-	-	-	-
3023 - Expert Witness			-			-	-	-	-	-	-
3088 - Inter-Agency Legal			-			-	-	-	-	-	-
3094 - Inter-Agency Hearing/Mediation			-			-	-	-	-	-	-
3000 - Services other								-	-	-	-
4000 - Commodities								-	-	-	-
Total Investigation Expenditures	-	-	-	-	-	-	-	-	-	-	-
Total Direct Expenditures	-	-	-	-	-	-	-	6,054	6,054	48,294	2,714
Indirect Expenditures											
Internal Administrative Costs			-			-		-	-	-	-
Departmental Costs			-			-		-	-	-	-
Statewide Costs			-			-		-	-	-	-
Total Indirect Expenditures	-	-	-	-	-	-	-	-	-	-	-
TOTAL EXPENDITURES	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ 6,054	$ 6,054	$ 48,294	$ 2,714
Cumulative Surplus (Deficit)											
Beginning Cumulative Surplus (Deficit)		$ -		$ -	$ -		$ -	$ -		$ 84,711	$ 62,567
Annual Increase/(Decrease)	-	-		-	-		-	84,711		(22,144)	164,201
Ending Cumulative Surplus (Deficit)	$ -	$ -		$ -	$ -		$ -	84,711		62,567	226,768
Statistical Information											
Number of Licenses for Indirect calculation								-	-	-	

Additional information:

- *Fee analysis required if the cumulative is less than zero; fee analysis recommended when the cumulative is less than current year expenditures; no fee increases needed if cumulative is over the current year expenses **
- *Most recent fee change: No fee change*
- *Annual license fee analysis will include consideration of other factors such as board and licensee input, potential investigation load, court cases, multiple license and fee types under one program, and program changes per AS 08.01.065.*

Appropriation Name (Ex)	(Multiple Items)
Sub Unit	(All)
PL Task Code	PDMP

Sum of Budgetary Expenditures	**Object Type Name (Ex)**		
Object Name (Ex)	**1000 - Personal Services**	**3000 - Services**	**Grand Total**
1011 - Regular Compensation	41,610.20		41,610.20
1014 - Overtime	705.66		705.66
1023 - Leave Taken	2,841.30		2,841.30
1028 - Alaska Supplemental Benefit	2,787.21		2,787.21
1029 - Public Employee's Retirement System Defined Benefits	221.77		221.77
1030 - Public Employee's Retirement System Defined Contribution	2,356.56		2,356.56
1034 - Public Employee's Retirement System Defined Cont Health Reim	1,624.09		1,624.09
1035 - Public Employee's Retiremnt Sys Defined Cont Retiree Medical	564.59		564.59
1037 - Public Employee's Retiremnt Sys Defined Benefit Unfnd Liab	5,221.94		5,221.94
1039 - Unemployment Insurance	84.66		84.66
1040 - Group Health Insurance	12,103.27		12,103.27
1041 - Basic Life and Travel	17.82		17.82
1042 - Worker's Compensation Insurance	423.20		423.20
1047 - Leave Cash In Employer Charge	927.00		927.00
1048 - Terminal Leave Employer Charge	625.78		625.78
1053 - Medicare Tax	636.86		636.86
1069 - SU Business Leave Bank Contributions	6.25		6.25
1077 - ASEA Legal Trust	59.77		59.77
1079 - ASEA Injury Leave Usage	1.90		1.90
1080 - SU Legal Trst	7.29		7.29
1970 - Personal Services Transfer	(71,055.78)		(71,055.78)
3002 - Memberships		300.00	300.00
3033 - Software Maintenance		18,668.76	18,668.76
3088 - Inter-Agency Legal		84.58	84.58
1979 - Personal Services Management Allocations	(219.79)		(219.79)
3970 - Contractual Transfer		(18,668.76)	(18,668.76)
3085 - Inter-Agency Mail		777.18	777.18
Grand Total	**1,551.55**	**1,161.76**	**2,713.31**

ADMIN BUSINESS

THE STATE of ALASKA
GOVERNOR MIKE DUNLEAVY

Department of Commerce, Community, & Economic Development

Corporations, Business, & Professional Licensing
Board of Pharmacy

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Alaska Board of Pharmacy
Authorized Emergency Courtesy License Activities

This document is to be used in reference to the Emergency Courtesy License (ECL) application, form #08-4757. The ECL is restricted in regulation to not be used as a substitute for permanent licensure. In addition, during its November 2020 meeting, the Alaska Board of Pharmacy authorized specific activities under this license category for urgent situations. An "urgent situation" is defined in 12 AAC 52.110 as a health crisis requiring an increased availability of pharmacists, pharmacy interns, or pharmacy technicians.

This list will continue to be updated as urgent situations arise and as they are authorized by the board.

Authorized Activity	Applicable to	As of	Ending
COVID-19 immunizations	Pharmacist, pharmacist intern, and pharmacy technician	November 6, 2020	

Board of Pharmacy Task List
(Tasks from previous meetings: February 18-19, 2020)

Number of tasks assigned	Completed	Pending
19		

No.	Task	Assigned	Status
1	Ms. Carrillo will send the November 5 – 6 and December 3- 4, 2020 meeting minutes for signature and request it to be posted on the Board's meeting page.	Laura Carrillo	Completed 02/23/2021
2	Ms. Carrillo will forward the revised PDMP disciplinary matrix to the investigative unit for their records.	Laura Carrillo	Completed on 02/23/2021.
3	Dr. Ruffridge will review the website FAQs for accuracy and applicability and recommend at the board's next meeting what FAQs need to be added, updated, removed, or turned into position statements.	Justin Ruffridge	By May 2021 meeting
4	Ms. Carrillo will follow up with Nancy Kavan to find out if she was referring to the jurisprudence questionnaire or the MPJE.	Laura Carrillo	Completed 02/23/2021
5	Ms. Carrillo will contact the NABP to register herself and Dr. Ruffridge for the 117th Annual Meeting.	Laura Carrillo (for self and Dr. Ruffridge)	Completed 02/24/2021
6	Ms. Carrillo will contact the NABP to inquire if exam writing can be split between multiple participants and what that process might entail.	Laura Carrillo (for Dr. Holt and Dr. Holm)	Completed 02/24/2021
7	Ms. Carrillo will work on the board's 2021 strategic plan for review and discussion during the May meeting.	Laura Carrillo	Completed 03/31/2021
8	Ms. Carrillo will reach out to Ms. Lindemuth about joining the PDMP Chairs Meeting.	Laura Carrillo (for Tammy Lindemuth)	Completed 02/24/2021
9	All board members will review the investigative checklist and sample letter in advance of the May meeting	All	By May 2021 meeting
10	Ms. Carrillo will follow-up with Ms. Dumas on amending centralized regulations to	Laura Carrillo	Initiated 02/24/2021; followed-up 04/05/2021

	include fingerprint fees for the Board of Pharmacy.		
11	Ms. Carrillo will reach out to OSMAP for how the standing order is being used and by whom, and where the source of the kids are coming from.	Laura Carrillo	Completed 02/24/2021
12	Ms. Carrillo will follow up with Deputy Director Walsh to request clarification on the Negative Implication Canon.	Laura Carrillo	Initiated 02/18/2021, followed up 02/25/2021 for May meeting; followed up 04/05/2021; Megyn will be available
13	Ms. Carrillo will forward to the board additional information surrounding the pharmacist applicant's request.	Laura Carrillo	Completed 02/18/2021
14	Ms. Carrillo will sign the affidavit of board action and certifying changes for the emergency to permanent regulation, 12 AAC 52.110, and will forward the documents to the regulations specialist.	Laura Carrillo	Completed 02/22/2021
15	Ms. Carrillo will sign the affidavit of board action and certifying changes for the PDMP registration timeframe proposed in 12 AAC 52.855, and will forward the documents to the regulations specialist.	Laura Carrillo	Completed 02/22/2021
16	Ms. Sherrell will request clarification from Appriss as to whether two-factor authentication is used successfully in other states.	Lisa Sherrell	Completed 02/19/2021
17	Ms. Carrillo will follow-up with the pharmacist inquiring about medications to fire departments/EMS and will provide information on where to learn more about DHSS' Medical Services division.	Laura Carrillo	Completed 02/25/2021
18	Ms. Carrillo will follow-up with DOL on remote order entry services performed my out-of-state pharmacies.	Laura Carrillo	Initiated 02/25/2021; Completed 04/06/2021
19	Ms. Carrillo will poll the board for available meeting dates in May and September.	Laura Carrillo	Completed; May date for 20-21; Sept date pending

STATUTES/ REGULATIONS

Statutes and Regulations
Pharmacy

February 2021

DEPARTMENT OF COMMERCE, COMMUNITY,
AND ECONOMIC DEVELOPMENT

DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING

Rev. 2/12/2021

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CHAPTER 80. PHARMACISTS AND PHARMACIES

Article

1. **The Board of Pharmacy (§§ 08.80.003 - 08.80.105)**
2. **Licensing and Registration (§§ 08.80.110 - 08.80.270)**
3. **Duties of Licensed Pharmacists (§§ 08.80.294 - 08.80.335)**
4. **Unlawful Acts (§§ 08.80.390 - 08.80.460)**
5. **General Provisions (§§ 08.80.470 - 08.80.490)**

ARTICLE 1. THE BOARD OF PHARMACY

Section

03. **Practice of pharmacy as a profession**
05. **Statement of purpose**
10. **Creation and membership of board; officers**
30. **Powers and duties of the board**
45. **Nonprescription drugs**
50. **Applicability of Administrative Procedure Act**
60. **Meetings of the board**
70. **Quorum**
80. **Expenses of members**
105. **Removal of board members**

Sec. 08.80.003. PRACTICE OF PHARMACY AS A PROFESSION. The practice of pharmacy is declared to be a professional practice affecting the public health, safety, and welfare and is subject to regulation and control in the public interest. It is further declared to be a matter of public interest that only qualified persons be permitted to engage in the practice of pharmacy, and to ensure the quality of drugs and related devices distributed in the state.

Sec. 08.80.005. STATEMENT OF PURPOSE. It is the purpose of this chapter to promote, preserve, and protect the public health, safety, and welfare by and through the effective control and regulation of the practice of pharmacy.

Sec. 08.80.010. CREATION AND MEMBERSHIP OF BOARD; OFFICERS. (a) There is created the Board of Pharmacy, composed of seven members, five of whom shall be pharmacists licensed in the state who have been actively engaged in the practice of pharmacy in the state for a period of three years immediately preceding their appointment. Two shall be persons with no direct financial interest in the health care industry. Whenever possible, the board shall include at least one member from each judicial district.

(b) An officer elected by the board serves a term of one year and may not serve more than four consecutive full terms in a specific office.

Sec. 08.80.020. Term of office. *[Repealed, Sec. 20 ch 80 SLA 1996.]*

Sec. 08.80.030. POWERS AND DUTIES OF THE BOARD. (a) The board is responsible for the control and regulation of the practice of pharmacy.

(b) In order to fulfill its responsibilities, the board has the powers necessary for implementation and enforcement of this chapter, including the power to

(1) elect a president and secretary from its membership and adopt rules for the conduct of its business;

(2) license by examination or by license transfer the applicants who are qualified to engage in the practice of pharmacy;

(3) assist the department in inspections and investigations for violations of this chapter, or of any other state or federal statute relating to the practice of pharmacy;

(4) adopt regulations to carry out the purposes of this chapter;

(5) establish and enforce compliance with professional standards and rules of conduct for pharmacists engaged in the practice of pharmacy;

(6) determine standards for recognition and approval of degree programs of schools and colleges of pharmacy whose graduates shall be eligible for licensure in this state, including the specification and enforcement of requirements for practical training, including internships;

(7) establish for pharmacists and pharmacies minimum specifications for the physical facilities, technical equipment, personnel, and procedures for the storage, compounding, and dispensing of drugs or related devices, and for the monitoring of drug therapy;

(8) enforce the provisions of this chapter relating to the conduct or competence of pharmacists practicing in the state, and the suspension, revocation, or restriction of licenses to engage in the practice of pharmacy;

(9) license and regulate the training, qualifications, and employment of pharmacy interns and pharmacy technicians;

(10) issue licenses to persons engaged in the manufacture and distribution of drugs and related devices;

(11) establish and maintain a controlled substance prescription database as provided in AS 17.30.200;

(12) establish standards for the independent administration by a pharmacist of vaccines and related emergency medications under AS 08.80.168, including the completion of an immunization training program approved by the board;

(13) establish standards for the independent dispensing by a pharmacist of an opioid overdose drug under AS 17.20.085, including the completion of an opioid overdose training program approved by the board;

(14) require that a licensed pharmacist register with the controlled substance prescription database under AS 17.30.200(o);

(15) establish the qualifications and duties of the executive administrator and delegate authority to the executive administrator that is necessary to conduct board business;

(16) license and inspect the facilities of wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

(c) The board shall post and maintain a link to the United States Food and Drug Administration's list of all currently approved interchangeable biological products on the board's Internet website.

(d) The minimum specifications for facilities, equipment, personnel, and procedures for the compounding, storage, and dispensing of drugs established under (b)(7) of this section must be consistent with the requirements of secs. 201 - 208, P.L. 113-54 (Drug Supply Chain Security Act).

Sec. 08.80.040. Duties of the board. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.045. NONPRESCRIPTION DRUGS. (a) Except as provided in (b) of this section the board may not regulate the sale of patent or nonprescription drugs that are prepackaged for use by the consumer, are in their original, unbroken packaging, and are labeled in accordance with requirements of the federal government.

(b) The board may regulate the sale and distribution of patent or nonprescription drugs under AS 44.62.250 when the regulation is required by an emergency to protect the public health and safety.

Sec. 08.80.050. APPLICABILITY OF ADMINISTRATIVE PROCEDURE ACT. The board shall comply with AS 44.62 (Administrative Procedure Act).

Sec. 08.80.060. MEETINGS OF THE BOARD. The board shall meet at least three times each year at the call of the president for the transaction of business properly before it. The president shall also call the board into session when requested in writing by at least two members. Meetings may be held telephonically.

Sec. 08.80.070. QUORUM. Four members constitute a quorum for the transaction of business. However, when the board meets for the purpose of examining applications for licensure, three members of the board constitute a quorum.

Sec. 08.80.080. EXPENSES OF MEMBERS. Members of the board are entitled to reimbursement for actual travel expenses incidental to the discharge of their duties and, while in the performance of their duties, are entitled to the per diem expenses allowed by law.

Sec. 08.80.090. Disposition of fees. *[Repealed, Sec. 54 ch 37 SLA 1985.]*

Sec. 08.80.100. Board secretary as certifying officer. *[Repealed, Sec. 3 ch 59 SLA 1966.]*

Sec. 08.80.105. REMOVAL OF BOARD MEMBERS. A member of the board may be removed from office by the governor for cause.

ARTICLE 2. LICENSING AND REGISTRATION

Section

110. Qualifications for licensure by examination
116. Internship and other training programs
120. Grading and content of examination
145. Reciprocity; license transfer
147. Renewal of licensure
150. Temporary license
155. Emergency permit
157. Licensing of facilities
158. Registration of pharmacies located outside of state
159. Licensing and inspection of facilities outside of state
160. Fees
165. Continuing education requirements
168. Administration of vaccines and related emergency medications

261. Disciplinary sanctions
270. Executive administrator of the board

Sec. 08.80.110. QUALIFICATIONS FOR LICENSURE BY EXAMINATION. An applicant for licensure as a pharmacist shall

(1) be fluent in the reading, writing, and speaking of the English language;

(2) furnish the board with at least two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(3) be a graduate of a college in a degree program approved by the board;

(4) pass an examination or examinations given by the board or acceptable to the board under the score transfer process administered by the National Association of Boards of Pharmacy;

(5) have completed internship training or another program that has been approved by the board or demonstrated to the board's satisfaction that the applicant has experience in the practice of pharmacy that meets or exceeds the minimum internship requirements of the board.

Sec. 08.80.115. Registration of pregraduate and postgraduate intern pharmacist. *[Repealed, Sec. 40 ch 177 SLA 1978.]*

Sec. 08.80.116. INTERNSHIP AND OTHER TRAINING PROGRAMS. (a) An applicant for licensure by examination shall obtain practical experience in the practice of pharmacy concurrent with or after college attendance, or both, under terms and conditions the board shall determine.

(b) The board shall establish licensure requirements for interns and standards for internship or other training programs that are necessary to qualify an applicant for the licensure examination and shall also determine the qualifications of preceptors used in practical experience programs.

Sec. 08.80.117. Malpractice insurance. *[Repealed, Sec. 7 ch 94 SLA 1980.]*

Sec. 08.80.120. GRADING AND CONTENT OF EXAMINATION. The examination or examinations shall be prepared to measure the competence of the applicant to engage in the practice of pharmacy. The board may employ, cooperate, and contract with an organization or consultant in the preparation and grading of an examination, but shall retain sole discretion and responsibility for determining which applicants have successfully passed the examinations.

Sec. 08.80.130. Reexamination. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.140. License by credentials. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.145. RECIPROCITY; LICENSE TRANSFER. If another jurisdiction allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in this section, the board may license as a pharmacist in this state a person licensed as a pharmacist in the other jurisdiction if the person

(1) submits a written application to the board on a form required by the board;

(2) is at least 18 years of age;

(3) is of good moral character;

(4) possesses at the time of the request for licensure as a pharmacist in this state the qualifications necessary to be eligible for licensure in this state;

(5) has engaged in the practice of pharmacy for at least one year or has met the internship requirements of this state within the one-year period immediately before applying for a license under this section;

(6) presents proof satisfactory to the board that the person is currently licensed as a pharmacist in the other jurisdiction and does not currently have a pharmacist license suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education credits;

(7) has passed an examination approved by the board that tests the person's knowledge of Alaska laws relating to pharmacies and pharmacists and the regulations adopted under those laws; and

(8) pays all required fees.

Sec. 08.80.147. RENEWAL OF LICENSURE. If a pharmacist fails to apply for renewal of a license within five years from the expiration of the license, the person must pass an examination for license renewal, except that a person who has continually practiced pharmacy in another state under a license issued by the authority of that state may renew an expired license in this state upon fulfillment of the requirements that may be established by the board.

Sec. 08.80.150. TEMPORARY LICENSE. The board shall adopt regulations regarding the issuance of a temporary license to practice pharmacy.

Sec. 08.80.155. EMERGENCY PERMIT. The board shall adopt regulations regarding the issuance of an emergency permit to practice pharmacy.

Sec. 08.80.157. LICENSING OF FACILITIES. (a) A facility engaged in the practice of pharmacy or in the manufacture, production, or wholesale distribution of drugs or devices, and a pharmacy where drugs or devices are dispensed, shall be licensed by the board, and shall renew the license at intervals determined by the board. If operations are conducted at more than one location, each location shall be licensed by the board.

(b) The board may by regulation determine the licensure classifications of facilities and establish minimum standards for the facilities.

(c) The board shall establish by regulation the criteria that a facility must meet to qualify for licensure in each classification. The board may issue licenses with varying restrictions to facilities when the board considers it necessary to protect the public interest.

(d) The board may deny or refuse to renew a license if it determines that the granting or renewing of the license would not be in the public interest.

(e) Licenses issued by the board are not transferable or assignable.

(f) The board shall specify by regulation the minimum standards for responsibility of a facility or pharmacy that has employees or personnel engaged in the practice of pharmacy or engaged in the manufacture, wholesale distribution, production, or use of drugs or devices in the conduct of its business.

(g) A licensed facility shall report to the board

(1) permanent closing;

(2) change of ownership, management, location, or pharmacist-in-charge of a pharmacy;

(3) theft or loss of drugs or devices as defined by regulations of the board;

(4) conviction of an employee of violation of a state or federal drug law;

(5) disasters, accidents, theft, destruction, or loss relating to records required to be maintained by state or federal law;

(6) occurrences of significant adverse drug reactions as defined by regulations of the board;

(7) other matters and occurrences the board may require by regulation.

(h) The board may suspend, revoke, deny, or refuse to renew the license of a facility or pharmacy on the following grounds:

(1) the finding by the board of violations of a federal, state, or local law relating to the practice of pharmacy, drug samples, wholesale or retail drug or device distribution, or distribution of controlled substances;

(2) a felony conviction under federal, state, or local law of an owner of the facility or pharmacy or of an employee of the facility or pharmacy;

(3) the furnishing of false or fraudulent material in an application made in connection with drug or device manufacturing or distribution;

(4) suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant for the manufacture or distribution of drugs or devices, including controlled substances;

(5) obtaining remuneration by fraud, misrepresentation, or deception;

(6) dealing with drugs or devices that are known or should have been known to be stolen drugs or devices;

(7) dispensing or distributing drugs or devices directly to patients by a wholesale drug distributor other than a pharmacy;

(8) violation of this chapter or a regulation adopted under this chapter.

(i) The board's regulations under (b) - (d) and (f) of this section may not establish more stringent licensing requirements for the facilities governed by AS 08.80.390 than are set out in AS 08.80.390.

(j) This section does not apply to the offices of physicians, osteopaths, podiatrists, physician assistants, advanced nurse practitioners, dentists, veterinarians, dispensing opticians, or optometrists.

(k) This section applies to wholesale drug distributors, third-party logistics providers, and outsourcing facilities located outside the state under AS 08.80.159.

Sec. 08.80.158. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF STATE. (a) A pharmacy located outside of the state that regularly ships, mails, or delivers prescription drugs to consumers in the state shall register with the board.

(b) A pharmacy registering with the board under (a) of this section shall furnish to the board annually

(1) the location, names, and titles of all principal corporate officers and of all pharmacists who are dispensing prescription drugs to residents of the state;

(2) a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, and a copy of the most recent report resulting from an inspection of the pharmacy by the regulatory or licensing agency of the jurisdiction in which the pharmacy is located;

(3) a sworn statement indicating that the pharmacy complies with all lawful directions and requests for information from the regulatory or licensing authority of the jurisdiction in which the pharmacy is licensed; and

(4) proof satisfactory to the board that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy.

(c) A pharmacy subject to this section shall, during its regular hours of operations, provide a toll-free telephone service to facilitate communication between persons in the state and a pharmacist at the pharmacy who has access to records concerning the dispensing of prescription drugs to persons in the state. The toll-free number and the hours that the service is available shall be disclosed on a label affixed to each container of drugs dispensed to persons in the state. The telephone service shall be available at least 40 hours a week and at least six days a week.

(d) The board may, after a hearing, deny, revoke, or suspend the registration of a pharmacy located outside of the state and subject to this section if the pharmacy fails to comply with the requirements of this section, AS 17.20.080 - AS 17.20.135, or AS 17.30.020 - 17.30.080, or if the license, permit, or registration of the pharmacy is denied, revoked, or suspended by the licensing or regulatory agency of the jurisdiction in which the pharmacy is located.

(e) A pharmacy located outside of the state that is subject to this section but is not registered with the board under this section may not ship, mail, or deliver prescription drugs into the state and may not advertise its services in the state.

(f) A pharmacy subject to this section shall appoint a registered agent in the state who is empowered to accept, on behalf of the pharmacy, process, notice, and demand required or permitted by law to be served upon the pharmacy. If the pharmacy fails to appoint an agent under this subsection, if the registered agent cannot with reasonable diligence be found at the registered office, or if the registration of the pharmacy is suspended or revoked, the commissioner of commerce and economic development is an agent upon whom process, notice, or demand may be served. Service is made upon the commissioner in the same manner as provided for corporations under AS 10.06.175(b), except that for the purposes of AS 10.06.175(b)(2)(A), the address shall be the last registered address of the pharmacy as shown by the records of the board.

(g) The board shall by regulation define "regularly" for this section.

Sec. 08.80.159. LICENSING AND INSPECTION OF FACILITIES OUTSIDE OF STATE. (a) Before shipping, mailing, or delivering prescription drugs to a licensee in the state or advertising in the state, a wholesale drug distributor, third-party logistics provider, or an outsourcing facility that is located outside the state shall

(1) obtain a license under AS 08.80.157;

(2) appoint an agent on whom process can be served in the state; and

(3) authorize inspection of the facility by a designee of the board under (c) of this section.

(b) In addition to the requirements of (a) of this section, an outsourcing facility shall

(1) register as an outsourcing facility with the United States Food and Drug Administration; and

(2) comply with the requirements of 21 U.S.C. 353b (Drug Quality and Security Act).

(c) Upon application by a wholesale drug distributor, third-party logistics provider, or an outsourcing facility for a license under this section, the board may

(1) require an inspection of the applicant's facility located outside the state; and

(2) approve a designee to conduct the inspection.

(d) The board shall adopt regulations necessary to implement this section.

Sec. 08.80.160. FEES. The Department of Commerce, Community, and Economic Development shall set fees under AS 08.01.065 for the following:

(1) examination;

(2) reexamination;

(3) investigation for licensing by license transfer;

(4) pharmacist license;

(5) temporary license;

(6) pharmacy technician license;

(7) pharmacy intern license;

(8) emergency permit;

(9) license amendment or replacement;

(10) registration or licensure of a facility classified under AS 08.80.157(b).

Sec. 08.80.165. CONTINUING EDUCATION REQUIREMENTS. The board shall establish requirements for continuing education in pharmacy that must be satisfied before a license issued under this chapter may be renewed.

Sec. 08.80.168. ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS.

(a) A pharmacist may independently administer a vaccine and related emergency medication if the pharmacist has completed an immunization training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(b) A pharmacist may independently dispense an opioid overdose drug if the pharmacist has completed an opioid overdose drug training program approved by the board and otherwise complies with the standards established by the board under AS 08.80.030(b).

(c) In this section,

(1) "opioid overdose drug" has the meaning given in AS 17.20.085;

(2) "related emergency medication" includes an epinephrine injection or other medication for the treatment of a severe allergic reaction to a vaccine.

Sec. 08.80.170-08.80.210. Fees. *[Repealed, Sec. 7 ch 24 SLA 1968.]*

Sec. 08.220. Prescription department required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.230. Sanitary conditions required for issuance of license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.240. Form and display of registration certificate and license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.250-08.80.260. Renewal of lapsed registration; ground for refusing or revoking a license. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.261. DISCIPLINARY SANCTIONS. (a) The board may deny a license to an applicant or, after a hearing, impose a disciplinary sanction authorized under AS 08.01.075 on a person licensed under this chapter when the board finds that the applicant or licensee, as applicable,

(1) secured or attempted to secure a license through deceit, fraud, or intentional misrepresentation;

(2) engaged in deceit, fraud, or intentional misrepresentation in the course of providing professional services or engaging in professional activities;

(3) advertised professional services in a false or misleading manner;

(4) has been convicted of a felony or has been convicted of another crime that affects the applicant's or licensee's ability to practice competently and safely;

(5) intentionally or negligently engaged in or permitted the performance of patient care by persons under the applicant's or licensee's supervision that does not conform to minimum professional standards regardless of whether actual injury to the patient occurred;

(6) failed to comply with this chapter, with a regulation adopted under this chapter, or with an order of the board;

(7) is incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety for the public because of

(A) professional incompetence;

(B) failure to keep informed of or use current professional theories or practices;

(C) addiction or severe dependency on alcohol or a drug that impairs the applicant's or licensee's ability to practice safely;

(D) physical or mental disability; or

(E) other factors determined by the board;

(8) engaged in conduct involving moral turpitude or gross immorality;

(9) made a controlled substance available to a person except upon prescription issued by a person licensed to prescribe controlled substances;

(10) was convicted of selling federal legend drugs without the prescription of a person licensed to prescribe federal legend drugs;

(11) violated state or federal laws or regulations pertaining to drugs or pharmacies;

(12) failed to report relevant information to the board about a pharmacist or pharmacy intern that the applicant or licensee knew or suspected was incapable of engaging in the practice of pharmacy with reasonable skill, competence, and safety to the public;

(13) aided another person to engage in the practice of pharmacy or to use the title of "pharmacist" or "pharmacy intern" without a license; or

(14) engaged in unprofessional conduct, as defined in regulations of the board.

(b) The board may place under seal all drugs that are owned by or in the possession, custody, or control of a licensee at the time a license is suspended or revoked or at the time the board refuses to renew a license. Except for perishable items, the drugs may not be disposed of until the licensee has exhausted administrative and judicial remedies relating to the licensing action. Perishable items may be sold upon order of the court with the proceeds to be deposited with the court. The board shall notify the Department of Health and Social Services about drugs placed under seal under this subsection.

Sec. 08.80.265. Limits or conditions on license; discipline. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.266. Disciplinary sanctions. *[Repealed, Sec. 49 ch 94 SLA 1987.]*

Sec. 08.80.270. EXECUTIVE ADMINISTRATOR OF THE BOARD. (a) The board shall employ an executive administrator to carry out the duties established under (b) of this section. The executive administrator is the principal executive officer of the board. The executive administrator is in the partially exempt service under AS 39.25.120 and is entitled to receive a monthly salary equal to a step in Range 23 on the salary schedule set out in AS 39.27.011(a).

(b) The executive administrator shall

(1) perform duties associated with the licensing and regulation of licensees under this chapter as prescribed by the board; and

(2) serve as a liaison to the legislative and executive branches of state government, the media, and other state pharmacy boards.

ARTICLE 3. DUTIES OF LICENSED PHARMACISTS

Section

294. Information about equivalent generic drugs and interchangeable biological products

295. Substitution of equivalent drug products or interchangeable biological products
297. Prescription prices and less costly alternatives
315. Confidentiality of records
330. Licensed pharmacist appointed as "pharmacist-in-charge"
335. Prescription for an opioid; voluntary request for lesser quantity

Sec. 08.80.270-08.80.290. Report of employees and goods sold; affixing labels. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.294. INFORMATION ABOUT EQUIVALENT GENERIC DRUGS AND INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) In addition to other information that may be required under state or federal laws or regulations, a pharmacist, when dispensing a brand-name prescription drug order that is

(1) not a biological product, shall include the generic drug name that is an equivalent drug product for the drug dispensed;

(2) a biological product, shall include the dispensed product's

(A) proprietary name, if available; or

(B) proper name.

(b) The generic drug name or proprietary or proper biological product name required under (a) of this section shall be placed directly on the container's label near the brand name.

(c) In this section,

(1) "proper name" means a name that reflects scientific characteristics of the product such as chemical structure and pharmacological properties;

(2) "proprietary name" means a name that is trademarked and registered for private use.

Sec. 08.80.295. SUBSTITUTION OF EQUIVALENT DRUG PRODUCTS OR INTERCHANGEABLE BIOLOGICAL PRODUCTS. (a) Unless the prescription indicates that it is to be dispensed only as written, the pharmacist may, with the consent of the patient, substitute an equivalent drug product or interchangeable biological product.

(b) A pharmacist who substitutes an equivalent drug product or interchangeable biological product in compliance with this section and applicable regulations incurs no greater liability in filling the prescription than would be incurred in filling the prescription by dispensing the prescribed name brand product.

(c) Except as provided in (d) of this section, if an interchangeable biological product exists for a biological product prescribed to a patient, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescribing practitioner information regarding the biological product provided to the patient, including the name and manufacturer of the biological product. The communication must be provided within three business days after dispensing the biological product as follows:

(1) by making an entry that is electronically accessible to the prescribing practitioner through

(A) an interoperable electronic medical records system;

(B) an electronic prescribing technology;

(C) a pharmacy benefit management system; or

(D) a pharmacy record; or

(2) if the pharmacist or the pharmacist's designee is unable to make an entry through one of the means provided under (1) of this subsection, by facsimile transmission, telephone communication, electronic mail transmission, or transmission by other prevailing means, to the prescribing practitioner.

(d) The dispensing pharmacist or the pharmacist's designee is not required to communicate information under (c) of this section if the dispensed biological product is a refill of a prescription and is the same as the biological product that was dispensed on the previous filling of the prescription.

(e) Entry into an electronic records system as described under (c)(1) of this section is presumed to provide notice to the prescribing practitioner.

(f) A pharmacist shall maintain a record of a dispensed biological product for a minimum of two years after the date of the dispensing.

(g) In this section, "designee" means an agent or employee of the dispensing pharmacist whom the dispensing pharmacist has authorized to communicate the information required under (c) of this section.

Sec. 08.80.297. PRESCRIPTION PRICES AND LESS COSTLY ALTERNATIVES. (a) A pharmacist shall disclose the price of filling any prescription when requested by the consumer.

(b) No contract or agreement may prohibit a pharmacy, pharmacist, or pharmacy benefits manager from informing a patient of a less costly alternative for a prescription drug or medical device or supply, which may include the amount the patient would pay without the use of a health care plan.

(c) A pharmacist or person acting at the direction of a pharmacist shall notify the patient if a known less costly alternative for a prescription drug or medical device or supply is available, which may include the amount the patient would pay without the use of a health care plan.

(d) In this section,

(1) "health care plan" means a policy, contract, benefit, or agreement that provides, delivers, arranges for, pays for, or reimburses any of the costs of health care services under

(A) a health care insurance plan as defined under AS 21.54.500;

(B) a governmental or employee welfare benefit plan under 29 12 U.S.C. 1001 - 1191 (Employee Retirement Income Security Act of 1974);

(C) a plan offered under AS 39.30.090 or 39.30.091;

(D) a federal governmental plan as defined under AS 21.54.500;

(E) the Medicaid or Medicare program; or

(F) a self-insured employer benefit plan;

(2) "pharmacy benefits manager" has the meaning given in AS 21.27.955.

Sec. 08.80.300. Record of prescriptions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.310. Record of sales. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.315. CONFIDENTIALITY OF RECORDS. Information maintained by a pharmacist in the patient's records or that is communicated to the patient as part of patient counseling is confidential and may be released only to

(1) the patient or as the patient directs;

(2) a practitioner or pharmacist when, in the pharmacist's professional judgment, release is necessary to protect the patient's health and well-being; and

(3) other persons or governmental agencies authorized by law to receive confidential information.

Sec. 08.80.320. Pharmacist required. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.330. LICENSED PHARMACIST APPOINTED AS "PHARMACIST-IN-CHARGE". (a) Each pharmacy shall have a pharmacist-in-charge. Whenever an applicable law or regulation requires or prohibits action by a pharmacy, responsibility shall be that of the owner and the pharmacist-in-charge, whether the owner is a sole proprietor, partnership, association, corporation, or otherwise. The pharmacist-in-charge shall ensure compliance with all laws and regulations governing the operation of the pharmacy. A licensed pharmacist appointed as pharmacist-in-charge of a pharmacy shall immediately advise the board of that appointment.

(b) A license may not be issued to a pharmacy unless there is a licensed registered pharmacist-in-charge whose name appears on the face of the license.

Sec. 08.80.335. PRESCRIPTION FOR AN OPIOID; VOLUNTARY REQUEST FOR LESSER QUANTITY. (a) A pharmacist filling a prescription for an opioid that is a schedule II or III controlled substance under federal law may, at the request of the individual for whom the prescription is written, dispense the prescribed opioid in a lesser quantity than prescribed.

(b) Nothing in this section shall be construed to prevent substitution of an equivalent drug under AS 08.80.295.

Sec. 08.80.340-08.80.370. Requirements for handling drugs; general prohibitions. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

ARTICLE 4. UNLAWFUL ACTS

Section

390. Pharmacists required in hospitals and clinics
400. Other licensees not affected
410. Use of term "pharmacist" prohibited
420. Certain advertising prohibited
430. Use of pharmacy symbols prohibited
450. Disciplinary action
460. Penalties

Sec. 08.80.380 Issuance of shopkeepers permits. *[Repealed, Sec. 21 ch 166 SLA 1980.]*

Sec. 08.80.390. PHARMACISTS REQUIRED IN HOSPITALS AND CLINICS. (a) A hospital, clinic, nursing home, infirmary, or related facility that provides dispensing of drugs for outpatient treatment shall have a licensed pharmacist in charge of the dispensary, except that prescriptions may be compounded and dispensed by or under the supervision of the prescribing physician.

(b) The board shall issue a license to a hospital drug room, nursing home drug room, or related facility that dispenses drugs from bulk supply for inpatient treatment, providing the facility employs a licensed pharmacist on a continual or consultant basis.

Sec. 08.80.400. OTHER LICENSEES NOT AFFECTED. This chapter does not affect the practice of medicine by a licensed medical doctor and does not limit a licensed medical doctor, osteopath, podiatrist, physician assistant,

advanced practice registered nurse, dentist, veterinarian, dispensing optician, or optometrist in supplying a patient with any medicinal preparation or article within the scope of the person's license.

Sec. 08.80.410. USE OF TERM "PHARMACIST" PROHIBITED. A person may not assume or use the title "pharmacist," or any variation of the title, or hold out to be a pharmacist, without being licensed.

Sec. 08.80.420. CERTAIN ADVERTISING PROHIBITED. (a) A person may not use or exhibit the title "pharmacist," "assistant pharmacist," or "druggist," or the descriptive term "pharmacy," "drug store," "drug sundries," or other similar title or term containing the word "drug," in any business premises, or in an advertisement through the media of press, or publication, or by radio or television, unless the business has a licensed pharmacist in regular and continuous employment.

(b) *Repealed 1980.*

Sec. 08.80.430. USE OF PHARMACY SYMBOLS PROHIBITED. A person may not display in a place of business the characteristic pharmacy symbol of "Rx" in any form unless the business has a pharmacist licensed under this chapter.

Sec. 08.80.440. Denial of examination or license. *[Repealed, Sec. 28 ch 45 SLA 1996.]*

Sec. 08.80.450. DISCIPLINARY ACTION. The board may consider a complaint based upon the alleged violation of any provision of this chapter, and may by a majority vote of a quorum dismiss the complaint, reprimand a licensee, or take other punitive action as the nature of the facts warrant. Orders issued by the board shall be in writing, signed by a majority and filed with the secretary of the board. The accused shall receive an authenticated copy of the order.

Sec. 08.80.460. PENALTIES. (a) Except for a violation of AS 08.80.297, a person who violates a provision of this chapter is guilty of a class B misdemeanor.

(b) A person who violates the provisions of AS 08.80.295 or 08.80.297 may be punished by a civil fine in an amount established by the board in a schedule or schedules establishing the amount of civil fine for a particular violation. The schedule or schedules shall be adopted by the board by regulation. Any civil fine imposed under this section may be appealed in the manner provided for appeals in AS 44.62 (Administrative Procedure Act).

ARTICLE 5. GENERAL PROVISIONS

Section

470. Construction
475. Federal facilities not affected
480. Definitions
490. Short title

Sec. 08.80.470. CONSTRUCTION. Nothing in this chapter amends, modifies, repeals or otherwise changes any provision of AS 11.71, AS 17.20 (the Alaska Food, Drug and Cosmetic Act), or AS 17.30.

Sec. 08.80.475. FEDERAL FACILITIES NOT AFFECTED. This chapter does not apply to the safe storage, preservation, dispensing, or control of drugs in a federally operated hospital or institution.

Sec. 08.80.480. DEFINITIONS. In this chapter, unless the context otherwise requires,

(1) "administer" means the direct application of a drug to the body of a patient or research subject by injection, inhalation, ingestion, or other means;

(2) "biological product" means a product that is applicable to the prevention, treatment, or cure of a disease or condition of human beings, and is a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or derivative of arsphenamine or any other trivalent organic arsenic compound;

(3) "board" means the Board of Pharmacy;

(4) "compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device (A) as the result of a practitioner's prescription drug order or initiative based on the relationship of the practitioner, patient, and pharmacist in the course of professional practice or (B) for the purpose of, or as an incident to, research, teaching, or chemical analysis and not for sale or dispensing; "compounding" also includes the preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns;

(5) "controlled substance" has the meaning given in AS 11.71.900;

(6) "deliver" or "delivery" means the actual, constructive, or attempted transfer of a drug or device from one person to another, whether or not for consideration;

(7) "device" means an instrument, apparatus, implement, machine, contrivance, implant, or other similar or related article, including a component part or accessory, that is required under federal law to bear the label "Caution: Federal or state law requires dispensing by or on the order of a physician";

(8) "dispense" or "dispensing" means the preparation and delivery of a drug or device to a patient or patient's agent under a lawful order of a practitioner in a suitable container appropriately labeled for subsequent administration to, or use by, a patient;

(9) "distribute" means the delivery of a drug or device other than by administering or dispensing;

(10) "drug" means an article recognized as a drug in an official compendium, or supplement to an official compendium; an article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animal; an article other than food, intended to affect the structure or function of the body of man or animal; and an article intended for use as a component of an article specified in this paragraph but does not include devices or their components, parts, or accessories;

(11) "drug regimen review" includes evaluation of the prescription drug order and patient record for

(A) known allergies;

(B) rational therapy-contraindications;

(C) reasonable dose and route of administration;

(D) reasonable directions for use;

(E) duplication of therapy;

(F) drug-drug, drug-food, and drug-disease interactions;

(G) adverse drug reactions; and

(H) proper utilization, including over- or under-utilization, and optimum therapeutic outcomes;

(12) "equivalent drug product" means a drug product that has the same established name, active ingredients, strength or concentration, dosage form, and route of administration and that is formulated to contain the same amount of active ingredients in the same dosage form and to meet the same compendia or other applicable standards for strength, quality, purity, and identity, but that may differ in characteristics such as shape, scoring configuration, packaging, excipients including colors, flavors, preservatives, and expiration time;

(13) "interchangeable biological product" means a biological product that the United States Food and Drug Administration has determined

(A) meets the standards for interchangeability under 42 U.S.C. 262(k)(4); or

(B) is therapeutically equivalent to another biological product under the most recent edition or supplement of the United States Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(14) "intern" means an individual who is

(A) currently licensed by this state to engage in the practice of pharmacy while under the personal supervision of a pharmacist and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist; or

(B) a graduate from a college of pharmacy who is currently licensed by the board for the purpose of obtaining practical experience as a requirement for licensure as a pharmacist;

(15) "labeling" means the process of preparing and affixing a label to a drug container, exclusive, however, of the labeling by a manufacturer, packer, or distributor or a nonprescription drug or commercially packed legend drug or device;

(16) "legend drug" means a prescription drug;

(17) "manufacturing" means the production, preparation, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction from a substance of natural origin or independently by means of chemical or biological synthesis, and includes packaging or repackaging of a substance or labeling or relabeling of its container, and the promotion and marketing of drugs or devices; "manufacturing" also includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons;

(18) "nonprescription drug" means a nonnarcotic medicine or drug that may be sold without a prescription and that is prepackaged for use by the consumer and labeled in accordance with the requirements of the statutes and regulations of the state and the federal government;

(19) "outpatient dispensing" means dispensing drugs for administration outside of the hospital pharmacy's control;

(20) "outsourcing facility" means a facility at one geographic location or address that is engaged in the compounding of sterile drugs for a facility at another geographic location;

(21) "owner" means the owner of a place of business for wholesaling, retailing, compounding, or dispensing drugs, medicines, or poisons;

(22) "patient counseling" means the communication by the pharmacist of information, as defined in the regulations of the board, to the patient or care giver in order to improve therapy by ensuring proper use of drugs and devices;

(23) "person" has the meaning given in AS 01.10.060 and also includes a governmental agency;

(24) "pharmaceutical care" is the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process as defined in regulations of the board;

(25) "pharmacist" means an individual currently licensed by this state to engage in the practice of pharmacy;

(26) “pharmacist-in-charge” means a pharmacist who accepts responsibility for operation of a pharmacy in a manner that complies with laws and regulations applicable to the practice of pharmacy and the distribution of drugs and who is personally in charge of the pharmacy and the pharmacy’s personnel;

(27) “pharmacy” means a place in this state where drugs are dispensed and pharmaceutical care is provided and a place outside of this state that is subject to licensure or registration under AS 08.80.157(b);

(28) “pharmacy located outside of the state” means a pharmacy that prepares or mixes prescription drugs outside of the state, regardless of the location at which those drugs may be shipped, mailed, or delivered to the consumer;

(29) “pharmacy technician” means a supportive staff member who works under the immediate supervision of a pharmacist;

(30) “practice of pharmacy” means the interpretation, evaluation, and dispensing of prescription drug orders in the patient's best interest; participation in drug and device selection, drug administration, drug regimen reviews, and drug or drug-related research; provision of patient counseling and the provision of those acts or services necessary to provide pharmaceutical care; the administration of vaccines and related emergency medication; the independent dispensing of opioid overdose drugs; the responsibility for compounding and labeling of drugs and devices except labeling by a manufacturer, repackager, or distributor of nonprescription drugs and commercially packaged legend drugs and devices; proper and safe storage of drugs and devices; and maintenance of proper records for them;

(31) “practitioner” means an individual currently licensed, registered, or otherwise authorized by the jurisdiction in which the individual practices to prescribe and administer drugs in the course of professional practice;

(32) “preceptor” means an individual who is currently licensed by the board, meets the qualifications as a preceptor under the regulations of the board, and participates in the instructional training of pharmacy interns;

(33) “prescription drug” means a drug that, under federal law, before being dispensed or delivered, is required to be labeled with either of the following statements: (A) “Caution: Federal law prohibits dispensing without prescription”; (B) “Caution: Federal law restricts this drug to use by, or on the order of, a licensed veterinarian”; or a drug that is required by an applicable federal or state law or regulation to be dispensed only under a prescription drug order or is restricted to use by practitioners only;

(34) “prescription drug order” means a lawful order of a practitioner for a drug or device for a specific patient;

(35) “prospective drug use review” means a review of the patient’s drug therapy and prescription drug order, as defined in the regulations of the board, before dispensing the drug as part of a drug regimen review;

(36) “significant adverse drug reaction” means a drug-related incident that may result in serious harm, injury, or death to the patient;

(37) “substitute” means to dispense, without the prescriber's expressed authorization,

(A) an equivalent drug product in place of the prescribed drug; or

(B) an interchangeable biological product in place of the prescribed biological product;

(38) “third-party logistics provider” means an entity that provides or coordinates warehousing or other logistics services for a product in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the product, and that does not take ownership of the product or have responsibility to direct the sale or disposition of the product;

(39) “wholesale” means sale by a manufacturer, wholesale dealer, distributor, or jobber to a person who sells, or intends to sell, directly to the user;

(40) “wholesale drug distributor” means anyone engaged in wholesale distribution of drugs, including manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers’ and distributors’ warehouses; chain drug warehouses; wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions.

Sec. 08.80.490. SHORT TITLE. This chapter may be known as the Pharmacy Act.

CHAPTER 52.
BOARD OF PHARMACY.

Article

1. **Licensing, Registration, and Permit Requirements (12 AAC 52.010 – 12 AAC 52.150)**
2. **Personnel (12 AAC 52.200 – 12 AAC 52.250)**
3. **License Renewal and Continuing Education Requirements (12 AAC 52.300 – 12 AAC 52.350)**
4. **Guidelines for Pharmacies and Pharmacists (12 AAC 52.400 – 12 AAC 52.445)**
5. **Pharmacy Practice Standards (12 AAC 52.450 – 12 AAC 52.590)**
6. **Wholesale Drug Distributors and Facilities (12 AAC 52.610 – 12 AAC 52.697)**
7. **Institutional Pharmacies (12 AAC 52.700 – 12 AAC 52.730)**
8. **Drug Rooms and Facilities Without a Pharmacy (12 AAC 52.800 – 12 AAC 52.850)**
9. **Controlled Substance Prescription Database (12 AAC 52.855 – 12 AAC 52.895)**
10. **Disciplinary Guidelines (12 AAC 52.900 – 12 AAC 52.980)**
11. **General Provisions (12 AAC 52.985 – 12 AAC 52.995)**

ARTICLE 1.
LICENSING, REGISTRATION, AND PERMIT REQUIREMENTS.

Section

10. Classifications of licensure
20. Facility license
30. Change of pharmacy location or name
40. Change of pharmacy ownership
50. Closed pharmacies
60. Fire or other disaster
70. Application for pharmacist license by examination
75. Good moral character
80. Internship requirements for a pharmacist license
90. Examination requirements and registration
92. Approval to sit for examination
95. Application for pharmacist license by reciprocity
100. Temporary pharmacist license
110. Emergency pharmacist permit
120. Review of pharmacist intern license application
130. Registration of pharmacies located outside of the state
140. Pharmacy technician license
150. Proof of licensure for individual pharmacists working for tribal health programs

12 AAC 52.010. CLASSIFICATIONS OF LICENSURE. (a) The board will issue the following categories of licenses or permits to a qualified individual:

(1) pharmacist license;
(2) temporary pharmacist license;
(3) emergency permit to practice pharmacy;
(4) pharmacist intern license;
(5) pharmacy technician license.

(b) The board will issue the following categories of licenses or registrations to a qualified facility:

(1) pharmacy license;
(2) repealed 2/26/2000;
(3) wholesale drug distributor license;
(4) drug room license;
(5) registration of a pharmacy located outside of the state;
(6) remote pharmacy license;
(7) third-party logistics provider license;

(8) outsourcing facility license;
(9) license of a wholesale drug distributor located outside of the state.

Authority: AS 08.80.005 AS 08.80.150 AS 08.80.158
AS 08.80.030 AS 08.80.155 AS 08.80.159
AS 08.80.116 AS 08.80.157 AS 08.80.390

12 AAC 52.020. FACILITY LICENSE. (a) An applicant for a facility license shall submit
(1) the fees required in 12 AAC 02.310;
(2) a completed application on a form provided by the department;
(3) within 14 days after commencement of business, a completed self-inspection of the premises questionnaire on a form provided by the department; and
(4) the name of the pharmacy or pharmacist that will provide consultant pharmacist services as required in AS 08.80.390, if applicable.
(b) Repealed 1/17/2007.
(c) An application for a remote or other pharmacy license must include the name of the pharmacist designated to be the pharmacist-in-charge as required in AS 08.80.330 and 12 AAC 52.200.
(d) An application for a pharmacy license must include the name and specific location of each remote pharmacy that will be under that pharmacy's control.
(e) An application for a remote pharmacy license must include the name and, if it has been issued, the license number of the pharmacy that is the central pharmacy.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.030. CHANGE OF PHARMACY LOCATION OR NAME. (a) The pharmacist-in-charge of a pharmacy that has changed its name or physical address shall apply for a new and separate pharmacy license. The applicant shall
(1) submit a new, completed application for a pharmacy license; and
(2) pay the duplicate license fee required in 12 AAC 02.105;
(3) repealed 1/17/2007.
(b) Within 14 days after commencement of business under the new license, the pharmacist-in-charge of a pharmacy that has changed its physical address shall complete a self-inspection questionnaire on a form provided by the department.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.040. CHANGE OF PHARMACY OWNERSHIP. (a) Repealed 1/17/2007.
(b) A new owner of a pharmacy shall apply for a new and separate facility license in accordance with 12 AAC 52.020.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.050. CLOSED PHARMACIES. (a) When a pharmacy ceases operations, the pharmacist-in-charge of that pharmacy shall
(1) submit written notice to the board of the cessation of pharmacy operations on a form provided by the department; the form must be submitted within 10 days after the cessation of operations and include
(A) the date the pharmacy ceased operations;
(B) a statement signed by the pharmacist-in-charge attesting that an inventory of all controlled substances on hand has been conducted; and
(C) a statement signed by the pharmacist-in-charge attesting to the manner of disposition for all prescription drugs possessed by the pharmacy;
(2) arrange for the transfer of prescription drug orders or computer prescription records to another pharmacy to facilitate continuous patient care; and
(3) provide for the maintenance and availability of prescription drug orders or hard copies of computer prescription records in accordance with 12 AAC 52.450(a) that are not transferred to another pharmacy;
(4) repealed 1/17/2007.
(b) In the absence of a pharmacist-in-charge, the owner of the pharmacy shall meet all requirements of this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.060. FIRE OR OTHER DISASTER. (a) If a pharmacy has a fire or other disaster, the pharmacist-in-charge of the pharmacy shall

(1) within 10 days, report to the board the date of a fire or any disaster that may affect the strength, purity, or labeling of drugs, devices, or other materials used in the practice of the pharmacy;

(2) provide the board with a copy of a completed DEA Form 106, "Report of Theft or Loss of Controlled Substances," reporting the loss or destruction of controlled substances or DEA order forms; if the extent of the loss of controlled substances cannot be determined, the pharmacist-in-charge shall submit to the board a complete inventory of all remaining controlled substances and a statement, signed by the pharmacist-in-charge, attesting to the accuracy of the inventory; and

(3) notify the board in writing within 10 days after any change in the pharmacy's address, including a move to a temporary location or a return to the pharmacy's permanent location.

(b) If a pharmacy maintains a temporary location for more than 90 days, the pharmacist-in-charge of the pharmacy shall apply for a new and separate facility license as required in 12 AAC 52.030.

(c) A pharmacy may not dispense any drug that has been exposed to excessive heat, smoke, or other conditions that may have caused deterioration.

(d) In this section, "other disaster" includes any disaster situation that causes a pharmacy the need to move to a temporary location or results in damage to the drug or device inventory.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030

12 AAC 52.070. APPLICATION FOR PHARMACIST LICENSE BY EXAMINATION. (a) An applicant who meets the requirements of AS 08.80.110, 08.80.116, and the requirements set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist license by examination. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by examination.

(b) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) verification that the applicant has completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080, sent directly to the department from the agency where the hours of internship or experience were completed;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

Editor's note: Information about accredited colleges of pharmacy may be obtained from the Accreditation Council for Pharmacy Education, 20 North Clark Street, Suite 2500, Chicago, IL 60602-5109. Information about Foreign Pharmacy Graduate Examination Committee certification and colleges recognized by that committee may be obtained from the National Association of Boards of Pharmacy, Foreign Pharmacy Graduate Examination Committee, 1600 Feehanville Drive, Mount Prospect, IL 60056.

12 AAC 52.075. GOOD MORAL CHARACTER. As used in AS 08.80, "good moral character" includes not having been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.080. INTERNSHIP REQUIREMENTS FOR A PHARMACIST LICENSE. (a) An applicant for a pharmacist license shall submit an affidavit signed by the applicant, on a form provided by the department, documenting completion of 1,500 hours of internship or experience in the practice of pharmacy.

(b) The board will accept as internship experience only internship hours completed under the direct supervision of a pharmacist licensed under AS 08.80 or the pharmacy licensing laws of another state.

(c) Repealed 4/16/2016.

(d) An internship program in a nontraditional site, such as an industry sponsored program, must be approved by the board before the board will give any internship credit for the program.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.090. EXAMINATION REQUIREMENTS AND REGISTRATION. (a) In addition to the requirements in AS 08.80.110, an applicant for a pharmacist license shall pass the

(1) North American Pharmacy licensing examination (NAPLEX) administered by the National Association of Boards of Pharmacy with a NAPLEX scaled score of 75 or above; and

(2) Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(b) An applicant for a temporary pharmacist license shall pass the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above.

(c) An applicant for a pharmacist license that has passed the NAPLEX examination in another licensing jurisdiction shall make arrangements for the National Association of Boards of Pharmacy to send verification of examination scores directly to the department.

(d) An applicant for licensure by examination must submit an application under 12 AAC 52.070 and be approved under 12 AAC 52.092 before sitting for examination under this section.

(e) An applicant who has failed the Alaska pharmacy jurisprudence examination specified in (f) of this section may not retake the examination for at least 30 days.

(f) The Multistate Pharmacy Jurisprudence Examination administered by the National Association of Boards of Pharmacy (NABP) is the examination adopted by the board as the Alaska pharmacy jurisprudence examination. An applicant shall satisfy all other license requirements within one year after passing the Alaska pharmacy jurisprudence examination or retake the examination.

(g) An applicant applying for a pharmacy license by examination shall make application within one year of successfully passing the NAPLEX. An applicant applying more than one year after passing the NAPLEX shall retake the NAPLEX or apply for a pharmacy license under AS 08.80.145.

Authority: AS 08.01.065 AS 08.80.110 AS 08.80.150
AS 08.80.005 AS 08.80.120 AS 08.80.160
AS 08.80.030

12 AAC 52.092. APPROVAL TO SIT FOR EXAMINATION. (a) An applicant for licensure by examination under 12 AAC 52.070 who has submitted documents that meet the requirements on the checklist set out in (b) of this section may be approved to sit for the North American Pharmacy Licensing Examination (NAPLEX) and the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090. An applicant whose application documents do not meet the requirements set out in (b) of this section will not be approved to sit for the NAPLEX or MPJE unless the board further reviews the application and determines that the applicant meets the requirements of AS 08.80.110, 08.80.116, and 12 AAC 52.070.

(b) The following checklist is established by the board for review by staff to determine if an applicant for a pharmacist license by examination may sit for examination. Except as provided in (a) of this section, an applicant for licensure by examination will be approved to sit for the NAPLEX and the MPJE if the applicant submits to the department

(1) a complete, notarized application on a form provided by the department; the application form must include a statement from the applicant attesting to the applicant's fluency in reading, writing, and speaking the English language;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records relating to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy, sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.110

12 AAC 52.095. APPLICATION FOR PHARMACIST LICENSE BY RECIPROCITY. (a) An applicant who meets the requirements of AS 08.80.145, the requirements set out in (b) of this section, and the requirements set out in (c) of this section has demonstrated the qualifications for a pharmacist license by reciprocity. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacist license by reciprocity will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacist license by reciprocity.

(b) An applicant for licensure under this section must show that the licensing jurisdiction where the applicant is licensed as a pharmacist allows licensure in that jurisdiction of a pharmacist licensed in this state under conditions similar to those in AS 08.80.145. A licensing jurisdiction that is a member of the National Association of Boards of Pharmacy meets the licensing jurisdiction reciprocity requirements of AS 08.80.145.

(c) An applicant for licensure under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12 AAC 02.310;

(3) on a form provided by the department, a signed authorization for the release of records related to the applicant's qualifications for licensure;

(4) either

(A) an official transcript, sent directly to the department from the applicant's college of pharmacy, that establishes that the applicant has received a professional degree from a college of pharmacy accredited by the ACPE; or

(B) a certified copy of

(i) the original pharmacy school diploma issued to the applicant; and

(ii) a Foreign Pharmacy Graduate Examination Committee certificate issued to the applicant by the National Association of Boards of Pharmacy sent directly to the department from the National Association of Boards of Pharmacy;

(5) two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character;

(6) either

(A) verification that, within the one-year period immediately preceding application for a license in this state, the applicant completed 1,500 hours of internship or experience in the practice of pharmacy that meet the requirements of 12 AAC 52.080; the verification must be sent directly to the department from the agency where the hours of internship or experience were completed; or

(B) verification that the applicant has engaged in the practice of pharmacy for at least one year in another licensing jurisdiction;

(7) verification that the applicant has passed the examinations required in 12 AAC 52.090, sent directly to the department by the National Association of Boards of Pharmacy;

(8) verification that the applicant is currently licensed as a pharmacist in another licensing jurisdiction and the applicant's license in the other jurisdiction is not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements;

(9) if the licensing jurisdiction in which the applicant is licensed as a pharmacist is a member of the National Association of Boards of Pharmacy, a copy of the applicant's Official Application for Transfer of Pharmaceutic Licensure, sent directly to the department from the National Association of Boards of Pharmacy;

(10) verification of the present status of the applicant's license in each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist.

(d) An applicant for licensure under this section who has not taken the Multistate Pharmacy Jurisprudence Examination (MPJE) required under 12 AAC 52.090 is approved to sit for that examination if the applicant has submitted the documents required under (c)(1) – (6) and (8) – (10) of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.145

12 AAC 52.100. TEMPORARY PHARMACIST LICENSE. (a) The board will issue a temporary pharmacist license to an applicant for licensure if the applicant

(1) submits a completed application for licensure;

(2) provides certified evidence of meeting the requirements in AS 08.80.110, AS 08.80.145, and this chapter;

(3) repealed 2/26/2000;

(4) provides for the National Association of Boards of Pharmacy (NABP) to notify the board that the applicant has submitted a preliminary application to NABP for license transfer;

(5) pays the application fee, pharmacist license fee, and temporary license fee required in 12 AAC 02.310;

(6) passes the Alaska pharmacy jurisprudence examination with a scaled score of 75 or above;

(7) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely; and

(8) submits a verification of a current license in good standing to practice in another state or other jurisdiction with licensing requirements at least equivalent to those of this state.

(b) An applicant whose application for permanent licensure as a pharmacist has been denied by the board is not eligible to receive a temporary license.

(c) A temporary license is valid for 90 days. For good cause shown to the board's satisfaction, the board will extend the temporary license for an additional period not to exceed 60 days.

(d) A temporary license is not renewable.

(e) An individual may not receive more than one temporary license.

Authority: AS 08.80.005 AS 08.80.145 AS 08.80.150
AS 08.80.030

12 AAC 52.110. EMERGENCY PHARMACIST PERMIT. (a) If the board determines that an emergency exists, the board will issue an emergency pharmacist permit for the purpose of providing coverage in a pharmacy that is temporarily without the services of a pharmacist due to death, illness, or other emergency circumstances, to an applicant who

(1) submits a completed application for a pharmacist license;

(2) pays the emergency permit fee required in 12 AAC 02.310;

(3) submits a certified true copy of a current pharmacist license in good standing in another state;

(4) repealed 10/31/2019; and

(5) has not been convicted of a felony or another crime that affects the applicant's ability to practice pharmacy competently and safely.

(b) An emergency permit is valid for 60 days or until the emergency circumstances no longer exist, whichever is shorter.

(c) An applicant may not receive more than one emergency permit. An emergency permit is not renewable.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.155

12 AAC 52.120. REVIEW OF PHARMACIST INTERN LICENSE APPLICATION. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacist intern license. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive a pharmacist intern license will not be issued a license unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that license.

(b) The following checklist is established by the board for review by staff of an application for a pharmacist intern license. A pharmacist intern license will be issued to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the application fee and the pharmacist intern license fee established in 12 AAC 02.310;

(3) has

(A) enrolled in a college of pharmacy accredited by the ACPE; or

(B) graduated from a college of pharmacy recognized by and earned certification from the Foreign Pharmacy Graduate Examination Committee of the National Association of Boards of Pharmacy;

(4) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to practice as a pharmacy intern competently and safely;

(5) repealed 10/31/2019;

(6) submits a completed authorization of release of records on a form provided by the department and signed by the applicant;

(7) submits a completed Alaska Jurisprudence Intern Practice Questionnaire prepared by the board covering the provisions of AS 08.80 and this chapter and 21 U.S.C. 801-847 (Controlled Substances Act); and

(8) submits two affidavits from reputable citizens that the applicant has known for at least one year attesting to the applicant's good moral character.

(c) A pharmacist intern license is valid for two years and may be renewed. An applicant for renewal of a pharmacist intern license must meet the requirements of (b)(1) and (2) of this section.

(d) An individual must be licensed as a pharmacist intern before beginning an internship in the state;

(e) A pharmacist intern license supersedes a pharmacy technician license and the pharmacy technician license shall be returned to the board.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.116
AS 08.80.030

12 AAC 52.130. REGISTRATION OF PHARMACIES LOCATED OUTSIDE OF THE STATE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary

qualifications for an out-of-state pharmacy registration. An applicant who does not meet the requirements on the checklist or whose application documents do not clearly show that the applicant is qualified to receive an out-of-state pharmacy registration will not be issued a registration unless the board further reviews the application and determines that the applicant meets the qualifications in AS 08.80 and this chapter for that registration.

(b) The following checklist is established by the board for review by staff of an application for an out-of-state pharmacy registration. An out-of-state pharmacy registration will be issued to an applicant who

(1) applies on an application provided by the department that includes

(A) the company name and owner name;

(B) the pharmacy name;

(C) the location of the facility;

(D) a mailing address and telephone number;

(E) a toll free number accessible by patients in this state;

(F) the federal employer identification number;

(G) the names of all partners or corporate officers;

(H) the name, address, and telephone number for pharmacist-in-charge;

(I) the names of all pharmacists working in the facility;

(J) completion of the professional fitness section of the application; and

(K) the name of the appointed registered agent;

(2) pays the application fee and the out-of-state pharmacy registration fee established in 12 AAC 02.310;

(3) submits a certified true copy of a current, valid facility license or registration from the jurisdiction where the pharmacy is located; and

(4) submits an inspection report or self-inspection report completed within the last two years.

(c) A pharmacy located outside of the state that ships, mails, or delivers prescription drugs into the state more than twice during a 12-month period shall register with the board.

(d) In AS 08.80.158(b)(4), "proof satisfactory" means a sworn statement that the pharmacy maintains its records of prescription drugs dispensed to persons in the state so that the records are readily retrievable from the records of other prescription drugs dispensed by the pharmacy, with either a written description or a copy of the pharmacy's policies and procedures.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.158

12 AAC 52.140. PHARMACY TECHNICIAN LICENSE. (a) An applicant who meets the requirements on the checklist set out in (b) of this section has demonstrated the necessary qualifications for a pharmacy technician license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a pharmacy technician license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a pharmacy technician license.

(b) The following checklist is established by the board for review of an application for a pharmacy technician license; a pharmacy technician license will be issued to an applicant who

(1) submits a completed form for application, including

(A) the applicant's name, mailing address, and telephone number; and

(B) the applicant's date of birth that shows the applicant is at least 18 years old;

(2) certifies that the applicant has not been convicted of a felony or another crime that affects the applicant's ability to perform the duties of a pharmacy technician safely and competently;

(3) certifies that the applicant has earned a high school diploma or its equivalent and provides the name of the issuing institution and the date the diploma or its equivalent was issued;

(4) certifies that the applicant is fluent in the reading, writing, and speaking of the English language; and

(5) pays the application fee and the pharmacy technician license fee established in 12 AAC 02.310.

(c) A pharmacy technician license expires on June 30 of even-numbered years and may be renewed.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.150. PROOF OF LICENSURE FOR INDIVIDUAL PHARMACISTS WORKING FOR TRIBAL HEALTH PROGRAMS. (a) A pharmacist who engages in the practice of pharmacy in a tribal health program in this state and who is not licensed by the board must provide the board notice that they are practicing under another license in accordance with 25 U.S.C. 1621t (sec. 221, Indian Health Care Improvement Act). Notice required under this section must be received no later than 30 days after an individual begins working at a tribal health program in this state, and must include

(1) a completed Alaska state pharmacist license exemption form provided by the department;

(2) a certified true copy of a current, valid pharmacist license in good standing from another jurisdiction; and

(A) proof of employment by a tribal health program that is operating under an agreement with the federal Indian Health Service under 25 U.S.C. 450 – 458ddd-2 (Indian Self-Determination and Education Assistance Act); or

(B) proof of status as an independent contractor, including a copy of the contract, if the out-of-state pharmacist is working for the tribal health program as an independent contractor.

(b) A pharmacist practicing under the exemption may not practice beyond the scope of the other state license.

(c) The licensing exemption does not extend to services provided to non-tribal health programs. In addition, an out-of-state licensed pharmacist working outside the scope of the individual's contracted employment with a tribal health program must apply for licensure as a pharmacist in accordance with AS 08.80.

Authority: AS 08.80.003 AS 08.80.005 AS 08.80.030

ARTICLE 2.
PERSONNEL.

Section

200. Pharmacist-in-charge
210. Pharmacist duties
220. Pharmacist interns
230. Pharmacy technicians
235. Pharmacy technician with national certification
240. Pharmacist collaborative practice authority
250. Job shadowing in pharmacy

12 AAC 52.200. PHARMACIST-IN-CHARGE. (a) Before the board will issue a license to a pharmacy, the owner of the pharmacy must designate a pharmacist who practices in that pharmacy location as the pharmacist-in-charge of the pharmacy in accordance with AS 08.80.330. For a remote pharmacy, the owner of the central pharmacy must designate a pharmacist in the central pharmacy as the pharmacist-in-charge of the remote pharmacy. The board will indicate the name of the pharmacist-in-charge on the face of the pharmacy license.

(b) The responsibilities of the pharmacist-in-charge include

(1) compliance with all laws and regulations governing the activities of the pharmacy;
(2) training of all pharmacy personnel;
(3) establishing policies and procedures for pharmacy operations;
(4) maintaining required records;
(5) storage of all materials, including drugs and chemicals;
(6) establishing and maintaining effective controls against theft or diversion of prescription drugs; and
(7) on request, reporting to the board the names of all pharmacists employed by the pharmacy.

(c) A pharmacist designated to replace the pharmacist-in-charge of a pharmacy shall notify the board within 10 days of that designation, by submitting a completed change of pharmacist-in-charge form provided by the department and paying the applicable fees established in 12 AAC 02.105(3).

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.330
AS 08.80.030 AS 08.80.160

12 AAC 52.210. PHARMACIST DUTIES. Except as provided in 12 AAC 52.220 and 12 AAC 52.235, the following duties may be performed only by a pharmacist:

(1) receiving an oral prescription drug order from a practitioner or authorized agent of a practitioner;
(2) consulting with a prescriber regarding a patient or prescription;
(3) interpreting a prescription drug order;
(4) determining the product required for a prescription;
(5) interpreting data in a patient medication record system;
(6) assuming the responsibility for a filled prescription;
(7) consulting with a patient or a patient's agent regarding a prescription or information contained in the patient medication record system; and
(8) administering a prescription drug order in accordance with the practitioner's order.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

12 AAC 52.220. PHARMACIST INTERNS. (a) A pharmacist intern may not represent that the pharmacist intern is a pharmacist. Only a person licensed by the board as a pharmacist intern may take, use, or exhibit the title of pharmacist intern or any other similar term.

(b) Except as provided in (c) of this section, a pharmacist intern may perform any duty of a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

(c) A pharmacist intern may not sign or initial any document that is required to be signed or initialed by a pharmacist unless the supervising pharmacist also signs or initials the document.

(d) A pharmacist intern shall file with the board a report of work experience on a form provided by the department within 30 days of completion or termination of an internship in the practice of pharmacy required under 12 AAC 52.080.

(e) A pharmacist supervising a pharmacist intern

(1) must be licensed as a pharmacist and be in good standing with the board;

(2) shall provide direct supervision to an intern during professional activities throughout the entire period of the internship;

(3) repealed 4/3/2020;

(4) is responsible for the work of the pharmacist intern;

(5) may supervise more than one pharmacist intern; more than one pharmacist intern may not dispense simultaneously under the direct supervision of the same supervising pharmacist.

Authority: AS 08.80.005 AS 08.80.110 AS 08.80.410
AS 08.80.030 AS 08.80.116

12 AAC 52.230. PHARMACY TECHNICIANS. (a) The following persons must be licensed as a pharmacy technician:

(1) an individual who assists in performing manipulative, nondiscretionary functions associated with the practice of pharmacy; and

(2) a supportive staff member assigned to work in the dispensing area of a pharmacy.

(b) A pharmacy technician shall work under the direct supervision of a person who is licensed as a pharmacist.

(c) Except as provided in 12 AAC 52.235, a pharmacy technician may not perform any of the duties listed in 12 AAC 52.210.

(d) An individual working as a pharmacy technician shall wear an identification badge that shows the individual's name and identifies the individual as a pharmacy technician.

(e) Before an individual may regularly perform the tasks of a pharmacy technician, the individual shall complete training required by the pharmacist-in-charge. Duties performed by the pharmacy technician must be consistent with the training the pharmacy technician has received.

(f) If a pharmacy technician will assist in the preparation of sterile pharmaceuticals, including parenteral medications, the pharmacy technician must have completed a minimum of 40 hours of on-the-job training in the preparation, sterilization, aseptic technique, and admixture of parenteral and other sterile pharmaceuticals before the pharmacy technician may regularly perform those tasks.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.235. PHARMACY TECHNICIAN WITH NATIONAL CERTIFICATION. (a) A pharmacy technician who holds a national certification may, at the direction of the pharmacist on duty and under the direct supervision of that pharmacist,

(1) perform a final check of and distribute a non-controlled substance prescription if

(A) the prescription drug order has previously undergone a drug regimen review by a pharmacist, including determination of substitution;

(B) the pharmacy uses a bar code scanning and verification system that confirms that the drug selected to fill the prescription is the same as indicated on the prescription label;

(C) the pharmacy uses software that displays the image or graphical description of the correct drug being verified; however, if there is any deviation between the image or graphical description and the actual product being distributed, a pharmacist must review and dispense the order; and

(D) each prescription distributed is electronically verified and the date and quantity distributed is documented in the patient record;

(2) transfer a non-controlled substance prescription drug order as described in 12 AAC 52.500; or

(3) clarify or obtain missing information from the practitioner or the practitioner's authorized agent on a non-controlled substance prescription drug order.

(b) Prescription drug order information clarifications under (a)(3) of this section must have the following information documented on the prescription drug order:

(1) the result of the clarification;

(2) the initials of the pharmacy technician who holds a national certification;

(3) the name of the practitioner or authorized agent that the pharmacy technician spoke to; and

(4) the date of the call.

(c) A pharmacy technician who holds a national certification may not sign or initial any document that is required to be signed or initialed by a pharmacist.

(d) In this section, "bar code scanning and verification system" means any technology that scans the bar code on a manufacturer drug container to ensure that the product being distributed matches the expectation of what was prescribed and inputted into the dispensing software.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.240. PHARMACIST COLLABORATIVE PRACTICE AUTHORITY. (a) A pharmacist planning to exercise collaborative practice authority in the pharmacist's practice by initiating or modifying drug therapy in accordance with a written protocol established and approved for the pharmacist's practice by a practitioner authorized to prescribe drugs under AS 08 must submit the completed written protocol to the board and be approved by the board before implementation.

(b) A written protocol must include

(1) an agreement in which practitioners authorized to prescribe legend drugs in this state authorize pharmacists licensed in this state to administer or dispense in accordance with that written protocol;

(2) a statement identifying the practitioners authorized to prescribe and the pharmacists who are party to the agreement;

(3) the time period during which the written protocol will be in effect, not to exceed two years;

(4) the types of collaborative authority decisions that the pharmacists are authorized to make, including

(A) types of diseases, drugs, or drug categories involved and the type of collaborative authority authorized in each case; and

(B) procedures, decision criteria, or plans the pharmacists are to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved;

(5) activities the pharmacists are to follow in the course of exercising collaborative authority, including documentation of decisions made, and a plan for communication and feedback to the authorizing practitioners concerning specific decisions made;

(6) a list of the specific types of patients eligible to receive services under the written protocol;

(7) a plan for the authorizing practitioners to review the decisions made by the pharmacists at least once every three months;

(8) a plan for providing the authorizing practitioners with each patient record created under the written protocol;

(9) a prohibition on the administration or dispensing of any schedule I, II, III, or IV controlled substances; and

(10) an acknowledgement that the authorizing practitioner will not receive any compensation from a pharmacist or pharmacy as a result of the care or treatment of any patient under the agreement.

(c) To enter into a written protocol under this section, practitioners authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioners' practice.

(d) Unless the board is satisfied that the pharmacist has been adequately trained in the procedures outlined in the written protocol, the board will specify and require completion of additional training that covers those procedures before issuing approval of the protocol.

(e) Documentation related to the written protocol must be maintained for at least two years.

(f) The written protocol may be terminated upon written notice by the authorizing practitioners or pharmacists. The pharmacists shall notify the board in writing within 30 days after a written protocol is terminated.

(g) Any modification to the written protocol must be approved by the board as required by this section for a new written protocol.

(h) This section does not apply to participation, by a pharmacist practicing in an institutional facility, in drug therapy protocols and guidelines approved by the institutional facility's pharmacy and therapeutics committee or by another medical staff governing body of that institutional facility, if records related to the drug therapy protocols and guidelines are maintained and made available to the board upon request.

(i) A signed copy of the approved collaborative practice application and protocols must remain at the pharmacy location at all times.

Authority: AS 08.80.030 AS 08.80.480

12 AAC 52.250. JOB SHADOWING IN PHARMACY. (a) A pharmacist-in-charge or job shadowing preceptor of a pharmacy may allow job shadowing by a student in the pharmacy only as specified in this section.

(b) Before a student begins a job shadowing program under this section, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board, which includes the names of the pharmacy, the participating student, and the pharmacist-in-charge or job shadowing preceptor. The student and the pharmacist-in-charge or preceptor, shall sign the form. The parent or guardian of the student shall also sign the form if the student is less than 18 years of age.

(c) The pharmacist-in-charge or, if applicable, the job shadowing preceptor shall familiarize the student with the confidentiality requirements of 45 C.F.R., Parts 160 and 164 (HIPAA) and ensure compliance with this section and the relevant sections of AS 08.80 and this chapter.

(d) A pharmacist-in-charge or job shadowing preceptor may not allow

(1) a student in a job shadowing program to

(A) receive any remuneration or other compensation;

(B) perform job shadowing for more than 50 hours;

(C) perform any functions reserved for licensed, certified, or registered pharmacy personnel;

(2) a ratio of job shadowing student to pharmacist-in-charge or job shadowing preceptor other than one to one.

(e) After completion of the job shadowing program by a student, the pharmacist-in-charge or job shadowing preceptor shall complete that portion of the job shadowing documentation form prescribed by the board where the pharmacist-in-charge or job shadowing preceptor provides the date and time in hours student was present and job shadowing in the pharmacy, any patient counseling observations, problems that may have occurred during job shadowing. The job shadowing documentation form must be kept in the pharmacy record for at least two years after the job shadowing program has been completed by that student.

(f) In this section,

(1) "job shadowing" means for educational purposes and through observation only, the observation by a student of the functions and duties of a pharmacy and pharmacy staff with the intended purpose of giving the student an opportunity to observe career possibilities available in the field of pharmacy;

(2) "job shadowing preceptor" means a licensed pharmacist, other than the pharmacist-in-charge, designated by the pharmacist-in-charge to supervise a student while that student is job shadowing;

(3) "student" means a person currently enrolled in a high school or post-secondary education program.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.330

Editor's note: The job shadowing documentation form required by 12 AAC 52.250 may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, P.O. Box 110806, Juneau, AK 99811-0806; phone: (907) 465-2589; or the division's website at http://www.commerce.state.ak.us/occ/ppha.htm.

ARTICLE 3.
LICENSE RENEWAL AND CONTINUING EDUCATION REQUIREMENTS.

Section

300. License renewal
310. Reinstatement of an expired pharmacist or pharmacy technician license
320. Continuing education requirements for pharmacists
325. Continuing education requirements for pharmacy technicians
330. Alternative continuing education schedule
340. Approved programs
350. Audit of records by the board

12 AAC 52.300. LICENSE RENEWAL. (a) Pharmacy, wholesale drug distributor, and drug room licenses expire on June 30 of even-numbered years.

(b) An applicant for renewal of a pharmacy, wholesale drug distributor, or drug room license shall submit

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) a completed self-inspection of the premises questionnaire on a form provided by the department.

(c) An applicant for renewal of a pharmacist or pharmacy technician license shall submit on or before the license expiration date

(1) a completed renewal application;

(2) the license renewal fees required in 12 AAC 02.310; and

(3) an attestation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350;

(4) repealed 4/3/2020.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.157
AS 08.80.005 AS 08.80.147 AS 08.80.165

12 AAC 52.310. REINSTATEMENT OF AN EXPIRED PHARMACIST OR PHARMACY TECHNICIAN LICENSE. (a) If a pharmacist's or pharmacy technician's license has expired for any reason, that pharmacist or pharmacy technician may not practice pharmacy until the license is reinstated by the board.

(b) The board will reinstate a pharmacist or pharmacy technician license that has been expired less than two years if the applicant submits

(1) a completed renewal application;

(2) any applicable license renewal fees required in 12 AAC 02.310;

(3) documentation that the applicant has met all continuing education requirements of 12 AAC 52.320 – 12 AAC 52.350; and

(4) for a licensing period that begins on or after July 1, 2006, a completed jurisprudence questionnaire prepared by the board, covering the provisions of AS 08.80 and this chapter.

(c) The board will reinstate a pharmacist license that has been expired two years or more if the applicant

(1) submits a completed application for reinstatement on a form provided by the department;

(2) pays any applicable license renewal fees required in 12 AAC 02.310 for the entire period the license has been expired;

(3) repealed 5/5/2000;

(4) submits evidence of completion of all continuing education requirements in 12 AAC 52.320 - 12 AAC 52.350 that would have been required to maintain a current license for the entire period the license has been expired;

(5) qualifies by

(A) retaking and passing the examinations required in 12 AAC 52.090(a); or

(B) providing verification that the applicant has continually practiced pharmacy in another state under a license issued by the authority of that state for the period that the license has been expired, and by meeting the requirements of 12 AAC 52.090(a)(2); for purposes of AS 08.80.147 and this subparagraph, an applicant has continually practiced pharmacy if the pharmacist has actively practiced pharmacy in the other state for at least six months during each year that the license in this state was lapsed; and

(6) submits a verification issued directly to the board by each licensing jurisdiction where the applicant holds, or has ever held, a license as a pharmacist during the time period in which the applicant's license was lapsed in this state that the applicant's license in the other jurisdiction were not suspended, revoked, or otherwise restricted except for failure to apply for renewal or failure to obtain the required continuing education requirements.

(d) Repealed 8/1/2014.

(e) A pharmacy technician license that has been expired for two years or more will not be reinstated.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005 AS 08.80.147

12 AAC 52.320. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACISTS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacist license shall certify having completed 30 contact hours of continuing education accepted by the board under 12 AAC 52.340(a) during the concluding license period.

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) An individual who is applying for renewal of a pharmacist license for the first time shall certify having completed one half of the continuing education requirements in (a) of this section for each complete 12 month period that the applicant was licensed during the concluding license period.

(d) An applicant for reinstatement of a pharmacist license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

(e) A pharmacist administering a vaccine or related emergency medication under 12 AAC 52.992 shall certify having completed one hour of Accreditation Council for Pharmacy Education (ACPE) approved continuing education specific to immunizations or vaccines as part of the 30 contact hours of continuing education required under (a) of this section.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.325. CONTINUING EDUCATION REQUIREMENTS FOR PHARMACY TECHNICIANS. (a) Except as provided in (c) of this section, an applicant for renewal of a pharmacy technician license shall certify that, during the concluding licensing period, the applicant

(1) completed 10 contact hours of continuing education accepted by the board under 12 AAC 52.340; or

(2) obtained initial certification as a pharmacy technician by the Pharmacy Technician Certification Board (PTCB).

(b) This section does not prevent the board from imposing additional continuing education requirements under its disciplinary powers.

(c) Instead of complying with the continuing education requirements in (a) of this section, an applicant for renewal of a pharmacy technician license for the first time may

(1) verify in an affidavit, on an application for renewal, that the applicant has read the state statutes and regulations compiled by the board; and

(2) submit an affidavit, signed by the pharmacist-in-charge, verifying the applicant's pharmacy technician training in accordance with 12 AAC 52.230.

(d) An applicant for reinstatement of a pharmacy technician license that has expired shall certify that the applicant completed the continuing education requirements in (a) of this section before applying for reinstatement.

Authority: AS 08.01.100 AS 08.80.030 AS 08.80.165
AS 08.80.005

Editor's note: Information regarding certification with the Pharmacy Technician Certification Board described in 12 AAC 52.325 may be obtained from the Pharmacy Technician Certification Board, 1100 15th Street, NW, Suite 703, Washington, DC 20005-1707, phone: (202) 429-4120 or at PTCB's website at www.ptcb.org. The Alaska Pharmacists Association, 203 West 15th Avenue, #100, Anchorage, AK 99501, phone: (907) 563-8880, email: akphrmcy@alaska.net also provides certification information.

12 AAC 52.330. ALTERNATIVE CONTINUING EDUCATION SCHEDULE. An individual licensed under AS 08.80 may apply to the board for an alternative schedule of continuing education if the individual's failure to meet the continuing education requirements in 12 AAC 52.320 is due to illness or other extenuating circumstances.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.165

12 AAC 52.340 APPROVED PROGRAMS. (a) The following programs will be accepted by the board as continuing education for pharmacists and pharmacy technicians under 12 AAC 52.320 and 12 AAC 52.325:

(1) any program presented by a provider accredited by the ACPE that results in a continuing education certificate showing the date of the course and the ACPE Universal Activity Number associated with the program;

(2) cardiopulmonary resuscitation(CPR) courses presented by the American Red Cross or the American Heart Association that lead to CPR certification; the board will accept no more than one contact hour of continuing education credit in a 24 month period for completion of a CPR course.

(b) The following programs will be accepted by the board as continuing education under 12 AAC 52.325, when the subject contributes directly to the professional competency of a pharmacy technician and is directly related to pharmacy principles and practice:

(1) any program presented or approved by the Alaska Pharmacists Association;

(2) any program presented or approved by the Pharmacy Technician Certification Board (PTCB) or the National Pharmacy Technician Association (NPTA).

(c) An individual who presents an approved continuing education program may receive credit for the time spent during the actual presentation of the program. An individual may not receive credit for the same presentation more than once during a licensing period.

Authority: AS 08.80.005 AS 08.80.147 AS 08.80.165
AS 08.80.030

12 AAC 52.350. AUDIT OF RECORDS BY THE BOARD. (a) The board will randomly audit renewal applications for verification of reported continuing education contact hours. To conduct an audit under this section, the board will access and evaluate continuing pharmacy education data reported to the ACPE-NABP CPE Monitor Service during the time period audited.

(b) Upon written request, a pharmacist or pharmacy technician shall provide the board with a copy of each certificate of completion for the continuing education units not reported to the ACPE-NABP CPE Monitor Service during the time period audited by the board.

(c) If the board disallows any continuing education contact units reported on behalf of or by a pharmacist or pharmacy technician, the pharmacist or pharmacy technician shall

(1) complete the number of disallowed contact hours in an approved program and report the completion to the board no later than 90 days after the date the board sends notification of the disallowed contact hours; and

(2) provide the board with copies of certificates of completion for all continuing education units

(A) not reported to the ACPE-NABP CPE Monitor Service; and

(B) completed for the next two licensing periods.

(d) A pharmacist or pharmacy technician who submits to the board a false or fraudulent record relating to the pharmacist's or pharmacy technician's satisfaction of a continuing education requirement under 12 AAC 52.320 or 12 AAC 52.325 is subject to disciplinary action by the board.

(e) In this section,

(1) "ACPE-NABP CPE Monitor Service" means the electronic tracking service of the ACPE and the National Association of Boards of Pharmacy for monitoring continuing pharmacy education that pharmacists and pharmacy technicians receive from participating providers;

(2) "certificate of completion" means a certificate or other document that

(A) is presented to a participant upon successful completion of a continuing education program that is not reported to the ACPE-NABP CPE Monitor Service; and

(B) contains the following information:

(i) the name of the participant;

(ii) the title and date of the program;

(iii) the name of the accredited provider;

(iv) the number of contact hours or continuing education units awarded;

(v) a dated, certifying signature of the accredited provider;

(vi) for a pharmacist renewal, the assigned ACPE universal program number.

Authority: AS 08.80.005 AS 08.80.165 AS 08.80.261
AS 08.80.030

ARTICLE 4.
GUIDELINES FOR PHARMACIES AND PHARMACISTS.

Section

400. General guidelines for pharmacies
410. Care of drug stocks and devices
420. Security
423. Remote pharmacy license
425. Telepharmacy system for a remote pharmacy

430. Guidelines relating to sterile pharmaceuticals
440. Guidelines relating to compounding practices
443. Approval for shared pharmacy services by pharmacy
444. Approval for shared pharmacy services by pharmacists
445. Shared pharmacy services
446. Shared pharmacy services during emergency

12 AAC 52.400. GENERAL GUIDELINES FOR PHARMACIES. A person that is required to be licensed by AS 08.80 and who has a license under AS 08.80 and this chapter shall adhere to the guidelines on facilities, reference material, equipment, supplies, and other guidelines established by the board in the pamphlet titled, "*Facility Standards for Pharmacies,*" dated November 2016, and incorporated by reference in this section.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.400, *"Facility Standards for Pharmacies"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.410. CARE OF DRUG STOCKS AND DEVICES. (a) A drug or device that has exceeded its expiration date shall be removed from stock and quarantined until properly disposed of in accordance with 12 AAC 52.560.

(b) A pharmacist may not dispense a drug or device beyond the expiration date on the drug or device.

(c) All drugs and devices on shelves or display for sale shall be protected against contamination, deterioration, and adulteration.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.420. SECURITY. (a) Each pharmacist, while on duty, is responsible for the security of the pharmacy, including effective control against theft or diversion of drugs.

(b) The pharmacist-in-charge is responsible for compliance with all prescription department security requirements.

(c) All drugs, devices, and other items or products that are restricted to sale by or under the direct supervision of a pharmacist shall be kept in the prescription department.

(d) The prescription department shall be secured to prevent unauthorized access when a pharmacist is not available to provide direct supervision.

(e) A pharmacy with service hours differing from the remainder of the business establishment must have a telephone number that is separate from the remainder of the business establishment.

(f) Prescriptions shall be stored in the prescription department and may be removed only under the direct supervision of a pharmacist and for immediate delivery to the patient, the patient's agent, or the person delivering the prescription to the patient or the patient's agent.

(g) A pharmacist shall provide adequate security for prescription records to prevent unauthorized access to confidential health information.

(h) In this section, "prescription department" means the area of the pharmacy where prescription drugs are stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.315
AS 08.80.030

12 AAC 52.423. REMOTE PHARMACY LICENSE. (a) A central pharmacy that wishes to provide pharmacy services through a remote pharmacy in the state using a telepharmacy system as provided in 12 AAC 52.425 must apply to the board for a license. The central pharmacy applying under this section must submit to the department

(1) a complete, notarized application on a form provided by the department;

(2) the applicable fees established in 12AAC 02.310; and

(3) comply with the requirements of 12 AAC 52.020.

(b) The board will approve an application to provide pharmacy services through a remote pharmacy if the central pharmacy establishes that

(1) it is able to comply with the requirements of 12 AAC 52.425; and

(2) there is no access to a non-remote pharmacy within ten road miles of the proposed remote pharmacy site unless the non-remote pharmacy is prevented by federal law from providing pharmacy services to all the individuals within the ten road miles.

(c) An applicant for renewal of a remote pharmacy license must comply with the requirements of 12 AAC 52.300.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.425. TELEPHARMACY SYSTEM FOR A REMOTE PHARMACY. (a) Only a pharmacist employed by a central pharmacy located in this state may provide pharmacy services to a remote pharmacy through a telepharmacy system. A telepharmacy system must be conducted under the direct supervision of a pharmacist located in this state. The pharmacist-in-charge of a remote pharmacy may supervise one or more remote pharmacies.

(b) Before a pharmacist employed by a central pharmacy may provide pharmacy services to a remote pharmacy, the telepharmacy system between the central pharmacy and remote pharmacy must be tested by the supervising pharmacist of the central pharmacy and found to operate properly. The supervising pharmacist of the central pharmacy shall make the results of the test available to the board upon request. The computer link and video link with sound of the telepharmacy system must include at least one of the following:

(1) still image capture;
(2) real time link;
(3) store and forward.

(c) A remote pharmacy must be

(1) staffed by a pharmacist, pharmacy technician, or pharmacy intern; and
(2) operated under the direct supervision of a pharmacist.

(d) A remote pharmacy must be secured to prevent unauthorized access at all times when a pharmacist is not available to provide direct supervision to that location.

(e) Drugs may be shipped to a remote pharmacy from the central pharmacy or a wholesale distributor. Drugs must be shipped in a sealed container with an itemized list of the product contained. The itemized list of drugs shipped must be kept on file at both the central pharmacy and the remote pharmacy for at least two years from the date that the drugs are shipped.

(f) A remote pharmacy must keep a record of all prescriptions filled at that location. The central pharmacy must have access to the records of the prescriptions dispensed by the remote pharmacy.

(g) The prescription label of a prescription drug dispensed by a remote pharmacy must meet the requirements of 12 AAC 52.480.

(h) Under a telepharmacy system a prescription drug is considered as being dispensed by the remote pharmacy. A prescription drug may not be dispensed by a remote pharmacy until a pharmacist employed by the central pharmacy has verified the finished prescription product through the telepharmacy system.

(i) A pharmacist must conduct a physical inventory at each remote pharmacy location at least annually. The record of the inventory must be

(1) kept both at the central pharmacy and the remote pharmacy; and
(2) distinguishable from the inventory of the central pharmacy and other remote pharmacies.

(j) Repealed 10/31/2019.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.430. GUIDELINES RELATING TO STERILE PHARMACEUTICALS. A pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals shall adhere to the guidelines established by the board in the pamphlet titled, "*Sterile Pharmaceuticals,"* dated February 2008, and incorporated by reference in this section.

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.430, *"Sterile Pharmaceuticals"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.440. GUIDELINES RELATING TO COMPOUNDING PRACTICES. A pharmacy or pharmacist that compounds drugs shall adhere to the guidelines established by the board in the pamphlet titled, "*Compounding Practices,"* dated February 2008, and incorporated by reference in this section

Authority: AS 08.80.030 AS 08.80.157

Editor's note: The pamphlet incorporated by reference in 12 AAC 52.440, *"Compounding Practices"* may be obtained from the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing, Board of Pharmacy, State Office Building, 9th Floor, 333 Willoughby Avenue, Juneau, Alaska 99801; phone (907) 465-2589.

12 AAC 52.443. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACY. (a) A requesting pharmacy in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacy to participate in shared pharmacy services if the pharmacy establishes

(1) that the pharmacy has a current in-state pharmacy license issued under AS 08.80.157 and this chapter;
(2) that the pharmacy is able to comply with the requirements of 12 AAC 52.445;

(3) that the pharmacy either

(A) is owned by the same owner as the filling pharmacy with which pharmacy services are to be shared; or

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligation of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(4) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.444. APPROVAL FOR SHARED PHARMACY SERVICES BY PHARMACIST. (a) A requesting pharmacist in this state that seeks to participate in shared pharmacy services must apply to the board for approval on a form provided by the department.

(b) The board will approve an application by a requesting pharmacist to participate in shared pharmacy services if the requesting pharmacist establishes

(1) that the pharmacist

(A) has a current in-state pharmacy license issued under AS 08.80 and this chapter;

(B) has a written contract or agreement with the filling pharmacy or filling pharmacist that outlines the pharmacy services to be provided and the obligations of each pharmacy or pharmacist to comply with federal and state pharmacy statutes and regulations; and

(C) is able to comply with the requirements of 12 AAC 52.445; and

(2) that the participants in shared pharmacy services share a common electronic file or other appropriate technology that allows access to the information needed to provide shared pharmacy services in compliance with the requirements of AS 08.80 and this chapter.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.445. SHARED PHARMACY SERVICES. (a) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall use an identifier on the prescription container that identifies prescriptions to be filled at a filling pharmacy or by the filling pharmacist. The requesting pharmacy or requesting pharmacist shall notify the patient or the patient's agent that the patient's prescription order may be processed or filled by another pharmacy or pharmacist, and shall identify the filling pharmacy or filling pharmacist. If the requesting pharmacy is part of a network of pharmacies under common ownership, and the prescription order may be processed or filled at any of the pharmacies in the network, the requesting pharmacy shall notify the patient of this. Notice under this subsection may be provided through an initial written notice to the patient or the patient's agent, or through the use of a sign prominently displayed in the requesting pharmacy or in the public portion of the office of the requesting pharmacist.

(b) Except as provided in (c) of this section, if a filling pharmacy or filling pharmacist delivers a prescription medication directly to the patient or the patient's agent, the filling pharmacy or filling pharmacist shall provide, on the prescription container or on a separate sheet delivered with the prescription container,

(1) the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist; and

(2) a statement that conveys to the patient or patient's agent the following information: "Written information about this prescription has been provided for you; please read this information before you take the medication. If you have questions concerning this prescription, a pharmacist is available during normal business hours to answer these questions at [insert the filling pharmacist or filling pharmacy's telephone numbers]."

(c) The requirements of (b) of this section do not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(d) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall

(1) maintain manual or electronic records identifying, individually for each order processed, filled, or dispensed, the name, initials, or identification code of each pharmacist responsible for the final verification of dispensing; those records must include descriptions of actions taken in interpretation of the order, order entry verification, drug utilization review, drug compatibility and drug allergy review, final order verification, therapeutic intervention, and refill authorization functions performed at that pharmacy or by that pharmacist;

(2) report to the board as soon as practical the results of any license disciplinary action taken by a regulatory agency in another licensing jurisdiction involving a pharmacy or pharmacist participating in shared pharmacy services;

(3) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy or by that pharmacist;

(4) provide for adequate security to protect the confidentiality and integrity of patient information;

(5) provide for inspection of any required record or information no later than 72 hours after any request by the board or its designee.

(e) Each pharmacy participating in shared pharmacy services, if a

(1) requesting pharmacy, shall have a current in-state pharmacy license issued under AS 08.80.157 and this chapter;

(2) filling pharmacy, shall either

(A) have a current in-state pharmacy license issued under AS 08.80.157 and this chapter; or

(B) be registered as an out-of-state pharmacy under AS 08.80.158 and this chapter.

(f) Each participant in shared pharmacy services shall jointly develop, implement, review, revise, and comply with joint policies and procedures for shared pharmacy services. Each participant is required to maintain only those portions of the joint policies and procedures that relate to that participant's operations. The policies and procedures must

(1) outline the responsibilities of each participant;

(2) include a list that contains

(A) each pharmacy participating in shared pharmacy services, and each pharmacist acting independently of a pharmacy and participating in shared pharmacy services;

(B) the name, address, and telephone number of each of those participants; and

(C) the license numbers for all licenses held by each of those participants; and

(3) address

(A) patient notification that meets the requirements of this section;

(B) the adequate protection of the confidentiality and integrity of patient information;

(C) dispensing prescription orders when the filled order is not received or the patient comes in before the order is received;

(D) the maintenance of manual or electronic records that meet the requirements of this section;

(E) compliance with federal and state laws; and

(F) the operation of a continuous quality improvement program for shared pharmacy services, designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

(g) Nothing in this section prevents an individual pharmacist licensed in this state who is employed by or working under a contract with a pharmacy, or prevents a licensed pharmacy intern or pharmacy technician working under the supervision of that licensed pharmacist, from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription order in compliance with AS 08.80 and this chapter if

(1) the pharmacy has established controls to protect the privacy and security of confidential records; and

(2) the pharmacist, pharmacy intern, or pharmacy technician does not duplicate, download, or remove data from the pharmacy's electronic database.

(h) A pharmacist working independently outside of the state may participate in shared pharmacy services with an institutional pharmacy in this state if the pharmacist holds

(1) a current license as a pharmacist issued under AS 08.80 and this chapter; and

(2) a current license to practice as a pharmacist issued by the licensing jurisdiction where the pharmacist is working.

(i) The pharmacist-in-charge of the requesting pharmacy must ensure compliance with the applicable requirements of AS 08.80 and this section.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.158
AS 08.80.030

12 AAC 52.446. SHARED PHARMACY SERVICES DURING EMERGENCY. (a) Notwithstanding 12 AAC 52.445, during a disaster emergency declared by the governor, a pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall do so in accordance with this section.

(b) During a disaster emergency declared by the governor, a pharmacist, pharmacist intern, or pharmacy licensed or registered under AS 08.80 may participate in shared pharmacy services without applying for approval under 12 AAC 52.443 and 12 AAC 52.444.

(c) Except as provided in (d) of this section, if a filling pharmacy or filling pharmacist or pharmacist intern delivers a prescription medication directly to the patient or the patient’s agent, the filling pharmacy or filling pharmacist or pharmacist intern shall provide, on the prescription container or on a separate sheet delivered with the prescription container, the local telephone number and, if applicable, the toll-free telephone number of the filling pharmacy or filling pharmacist.

(d) The requirement of (c) of this section does not apply to prescription medication delivered to patients in facilities where a licensed health care professional is responsible for administering the prescription medication to the patient.

(e) A pharmacy participating in shared pharmacy services, or a pharmacist acting independently of a pharmacy and participating in shared pharmacy services, shall maintain manual or electronic records identifying, individually for each order processed, filled or dispensed,

(1) the name, initials, or identification code of each pharmacist or pharmacist intern responsible for the final verification of dispensing; and

(2) the patient, date, drug, strength, directions, and quantity dispensed.

(f) A pharmacy participating in shared pharmacy services that distributes prescription drug orders under 12 AAC 52.235 using a pharmacy technician who holds a national certification shall maintain manual or electronic records identifying, individually for each order processed, filled, or distributed

(1) the name, initials, or identification code of each pharmacy technician who holds a national certification; and

(2) the patient, date, drug, strength, directions, and quantity distributed.

(g) Nothing in this section prevents a pharmacist who is employed by or working under a contract with the pharmacy, or prevents a licensed pharmacist intern or pharmacy technician from accessing the electronic database of that pharmacy from inside or outside the pharmacy and processing a prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

ARTICLE 5.
PHARMACY PRACTICE STANDARDS.

Section

450. Prescription drug order records
460. Prescription drug order information
465. Controlled substance prescription drug orders
470. Refills
480. Labeling
490. Prescriptions by electronic transmission
500. Transfer of a prescription drug order
510. Substitution
520. Customized patient medication package (patient med-pak)
530. Return or exchange of drugs
540. Notification of theft or significant loss
550. Advertising
560. Destruction and disposal of drugs
570. Drug regimen review
580. Data processing systems
585. Mandatory patient counseling
590. Prepackaging of drugs

12 AAC 52.450. PRESCRIPTION DRUG ORDER RECORDS. (a) A pharmacy shall maintain prescription drug orders for a period of two years from the date of filling or the date of the last dispensed refill. The prescription drug orders shall be maintained in a manner that ensures they will remain legible for the required two-year period.

(b) To comply with (a) of this section, a pharmacy shall maintain the prescription drug orders by

(1) keeping the original hard copy prescription drug order presented by a patient;

(2) keeping a plain paper version of the prescription drug order received by facsimile or digital electronic transmittal;

(3) keeping a prescription drug order put into writing either manually or electronically by the pharmacist; or

(4) electronically storing and maintaining the prescription drug order in a readily retrievable format.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.460. PRESCRIPTION DRUG ORDER INFORMATION. (a) Before a pharmacist may fill a prescription drug order, the pharmacist shall obtain the following information:

(1) name of the patient or, if the prescription drug order is for an animal, species of the animal and name of the owner;

(2) address of the patient unless the prescription drug order is for a noncontrolled substance and the address is readily retrievable on another appropriate, uniformly maintained pharmacy record, such as a patient medication record;

(3) name and, if the prescription drug order is for a controlled substance, the address and DEA registration number of the prescribing practitioner;

(4) name and strength of the drug prescribed;

(5) quantity prescribed;

(6) directions for use;

(7) date of issue;

(8) refills authorized, if any;

(9) if a written or hard copy prescription drug order, the prescribing practitioner's handwritten, digital, electronic, or stamped signature;

(10) if a prescription drug order is received by the pharmacy as a facsimile, the prescribing practitioner's handwritten, digital, electronic, or stamped signature, or authorized agent's signature; and

(11) if the prescription drug order is signed by an authorized agent, the name of the prescribing practitioner.

(b) At the time of dispensing, a pharmacist shall add the following information to the prescription drug order:

(1) unique identification number of the prescription drug order;
(2) initials or identification code of the dispensing pharmacist;
(3) quantity dispensed, if different from the quantity prescribed;
(4) date of dispensing, if different from the date of issue;
(5) if the drug was prescribed by generic name or if an equivalent drug product other than the one prescribed was dispensed, for the drug product actually dispensed, at least one of the following:
(A) the name of the drug product's manufacturer or distributor;
(B) the national drug code number;
(C) the short name code; or
(D) the trade name.

(c) After oral consultation with the prescribing practitioner, a pharmacist may add the following information to schedule II controlled substance prescriptions:
(1) date of issue of the prescription;
(2) address of the patient;
(3) strength of the drug prescribed;
(4) drug dosage form;
(5) drug quantity prescribed;
(6) directions for use;
(7) DEA registration number.

(d) After oral consultation with the prescribing practitioner, a pharmacist may modify the types of information described in (c)(2) – (7) of this section. However, any modification to the information concerning drug quantity must be limited to strength of the drug prescribed and may not result in an increase in the original total dosage prescribed.

(e) A pharmacist may not change the name of non-generic drugs, the name of the patient, or the signature of the practitioner.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.465. CONTROLLED SUBSTANCE PRESCRIPTION DRUG ORDERS. A prescription drug order for a schedule II controlled substance may be partially filled if prescribed for
(1) a terminally ill patient or a patient residing in a long term care facility, in accordance with 21 C.F.R. 1306.13; or
(2) a patient who is not terminally ill or residing in a long term care facility if
(A) the partial fill is requested by the patient or the practitioner that wrote the prescription;
(B) the total quantity dispensed in all partial filling does not exceed the total quantity prescribed;
(C) each partial fill is electronically documented in the patient record;
(D) the remaining portions are filled not later than 30 days after the date on which the prescription is written; and
(E) each partial fill only occurs at the pharmacy where the original prescription order is on file.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.470. REFILLS. (a) Repealed 4/3/2020.

(b) Repealed 4/3/2020.

(c) Each time a prescription drug order refill is dispensed, the pharmacist or pharmacist intern shall record the quantity and date of the dispensing.

(d) A pharmacist or pharmacist intern may dispense any quantity of a prescription drug order so long as the
(1) total quantity of dosage units dispensed does not exceed the total quantity of dosage units authorized by the prescriber on the prescription, including refills; and
(2) drug is not a federal or state scheduled controlled substance.

(e) To indicate that an increased supply may not be dispensed under this section, a prescriber may indicate "no change to quantity", or words of similar meaning, on the prescription drug order.

(f) Nothing in this section requires a health care service plan, health insurer, workers' compensation insurance plan, pharmacy benefits manager, or any other person or entity, including a state program or state employer, to provide coverage for a drug in a manner inconsistent with a beneficiary's plan benefit.

(g) Under (d) of this section, if the total quantity of a drug or device to dispense on an existing, chronic, non-controlled substance prescription drug order has been exhausted and the pharmacist is unable to reach the practitioner, a pharmacist or pharmacist intern may continue to dispense a quantity not to exceed a 120-day supply. In this section,
(1) "existing" means the pharmacy has record of a previous prescription drug order or the pharmacist can validate the prescription drug order from another pharmacy or patient labelled product;
(2) "chronic" means a drug that the patient takes regularly, for greater than three months.

(h) Under (g) of this section, the pharmacist must
(1) reduce the patient's prescription drug order to a written prescription drug order using the previously verified prescription drug order information and practitioner name;
(2) document "continuation of therapy", "COT", or words of similar meaning on the prescription drug order; and

(3) file and maintain the prescription in accordance with 12 AAC 52.450.

(i) A pharmacist may not dispense a refill of a prescription drug order for a noncontrolled substance after one year from the date of issue of the original prescription drug order.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.480. LABELING. One or more labels containing the following information shall be affixed to every container in which a prescription drug order is dispensed:

(1) name, address, and phone number of the dispensing pharmacy;

(2) unique identification number of the prescription drug order;

(3) date the prescription drug order is dispensed;

(4) initials, which may be handwritten, of the dispensing pharmacist or pharmacist intern;

(5) name of the prescribing practitioner;

(6) name of the patient or, if the drug was prescribed for an animal, the species of animal and the name of the owner;

(7) directions for use;

(8) quantity dispensed;

(9) appropriate ancillary instructions or cautions;

(10) if the prescription drug order is for a schedule II-V controlled substance, the statement, "Caution: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed";

(11) the name and strength of the actual drug product dispensed, unless otherwise directed by the prescribing practitioner;

(12) the accepted generic drug name and strength of the drug dispensed; if the drug product dispensed has multiple ingredients, the pharmacist shall provide this information in writing to the patient or the patient's agent.

Authority: AS 08.80.005 AS 08.80.295 AS 08.80.480
AS 08.80.030

12 AAC 52.490. PRESCRIPTIONS BY ELECTRONIC TRANSMISSION. (a) Legend drug, device, and controlled substance prescriptions may be transmitted electronically under this section, consistent with state and federal laws. A pharmacist or pharmacist intern may dispense a prescription transmitted electronically under this section only if the prescribing practitioner includes the following information on the prescription before it is transmitted:

(1) name, address, and telephone number of the prescribing practitioner;

(2) electronic signature or manual signature of the prescribing practitioner;

(3) the information required in 12 AAC 52.460(a)(1) - (8); and

(4) any other information required by federal law.

(b) A pharmacist may dispense a prescription that has been received electronically.

(c) The system for electronic transmission of prescriptions must address the following:

(1) patient's choice of pharmacy; the system may not restrict the patient's choice of pharmacy;

(2) security of the system; the system must have security and system safeguards designed to prevent and detect unauthorized access, modification, or manipulation of prescription information; the system must include

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other applicable equipment from an unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control, and audit access to confidential patient information; and

(D) processes to prevent unauthorized access to the prescription information when transmitted electronically;

(3) confidentiality of patient information; the system must maintain the confidentiality of patient information consistent with state and federal laws;

(4) authentication; to be valid prescriptions transmitted by an authorized prescriber or the prescribing practitioner's authorized agent from computer to a facsimile machine or from computer to computer must use an electronic signature; the prescribing practitioner's system must authenticate the sender's authority and credentials to transmit a prescription to a pharmacy and

(A) the prescribing practitioner's system must provide an audit record of all prescriptions electronically transmitted that documents for retrieval all actions and persons who have acted on a prescription, including authorized delegation of transmission;

(B) the right of the board to access the prescribing practitioner's electronically transmitted prescriptions for purposes of investigations;

(5) a prescribing practitioner's system that utilizes intermediaries in the electronic communication of prescriptions to pharmacies is responsible to ensure that the contracts with the intermediaries require security measures that are equal to or better than those provided by this section and prohibit the modification of a record of a prescription after it has been transmitted by the prescribing practitioner to the pharmacist;

(6) if a paper copy prescription that is generated by the pharmacist or pharmacy technician from the electronic prescription system is printed, an electronic signature may be substituted for a manual signature;

(7) the system must maintain the integrity and confidentiality of patient information transmitted electronically for its system as required by this chapter, other state law, and federal law.

(d) In this section,

(1) "electronic signature" means an electronic sound, symbol, or process attached to or logically associated with a prescription and executed or adopted by an authorized person with the intent to sign the prescription;

(2) "electronic transmission of prescriptions" means the communication from an authorized prescribing practitioner or the prescribing practitioner's authorized agent to a pharmacy of the patient's choice, by computer, by the transmission of an exact visual image of a prescription by facsimile, or by other electronic means other than electronic voice communication, of original prescription information or prescription refill information for a legend drug or controlled substance consistent with this section, other state law, and federal law;

(3) "security" means a system to maintain the confidentiality and integrity of prescription information, including

(A) documented formal procedures for selecting and executing security safeguards;

(B) physical safeguards to protect computer systems and other pertinent equipment from unauthorized access, modification, or manipulation of the information;

(C) processes to protect, control and audit access to confidential patient information; and

(D) processes for its system to prevent unauthorized access to the prescription information when transmitted electronically.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.500. TRANSFER OF A PRESCRIPTION DRUG ORDER. (a) For the purpose of dispensing a prescription drug order, original prescription drug order information may be transferred between pharmacies if the requirements of 12 AAC 52.460 and this section are met.

(b) Original prescription drug order information for controlled substances listed in schedules III, IV, or V may be transferred only by the pharmacy that originally received the prescription drug order from the prescribing practitioner. The transfer must be communicated directly between two licensed pharmacists.

(c) Original prescription drug order information for noncontrolled substances may be transferred verbally, electronically, or by means of facsimile between pharmacies without limitation up to the number of originally authorized refills.

(d) A pharmacy transferring a prescription drug order or receiving a transferred prescription drug order must meet the following requirements:

(1) repealed 4/3/2020;

(2) both the original and the transferred prescription drug order must meet the requirements of 12 AAC 52.450(a);

(3) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information shall record the following information:

(A) the name, address, and if a controlled substance, the DEA registration number of the pharmacy receiving the prescription drug order information;

(B) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the prescription drug order information;

(C) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(D) the date of the transfer;

(4) the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification receiving the transferred prescription drug order information shall record the following information:

(A) the original date of issue;

(B) the original unique identification number of the prescription;

(C) the quantity of drug or device remaining;

(D) the name, address, and if a controlled substance, the DEA registration number of the pharmacy transferring the prescription drug order information; and

(E) the name of the pharmacist, pharmacist intern, or pharmacy technician who holds a national certification transferring the prescription drug order information; and

(5) when a prescription drug order is transferred, the transferring pharmacy may not issue any further dispensing from that prescription drug order.

(e) A pharmacy using an automated data processing system shall meet the same requirements for a manual prescription drug order transfer listed in (d) of this section.

(f) If two or more pharmacies use a common electronic database for prescription record keeping, prescription drug orders may be refilled at any of the pharmacies using the common electronic database if provisions are made

(1) for an audit trail that documents the location of each filling; and

(2) to ensure that the total quantity dispensed from the prescription drug order does not exceed the total quantity authorized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.510. SUBSTITUTION. (a) A pharmacist or pharmacist intern may dispense an equivalent drug product or interchangeable biological product instead of the prescribed drug if

(1) the prescribing practitioner does not indicate on the prescription drug order that a specific brand must be dispensed, using language such as "brand medically necessary", "dispense as written", "do not substitute", or other similar wording indicating that the practitioner does not want it substituted;

(2) the patient is notified and consents to the substitution;

(3) repealed 10/31/2019; and

(4) for the drug product actually dispensed, the pharmacy record contains one of the following:

(A) the drug product's manufacturer or distributor;

(B) national drug code number;

(C) short name code; or

(D) trade name.

(b) The determination of the drug product to be dispensed for a prescription drug order is a professional responsibility of the pharmacist. A pharmacist may not dispense any product that in the pharmacist's professional opinion is not an equivalent drug product as the term "equivalent drug product" or "interchangeable biological product" is defined in AS 08.80.480.

(c) Nothing in this section prohibits a patient from requesting the original trade product instead of the substituted product if there is nothing on the prescription drug order from the prescribing practitioner that indicates that the practitioner wants only the substituted product dispensed.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.295

12 AAC 52.520. CUSTOMIZED PATIENT MEDICATION PACKAGE (PATIENT MED-PAK). (a) Instead of dispensing one or more prescribed drug products in separate containers, a pharmacist may, with the written consent of the patient, patient's caregiver, or prescribing practitioner, provide a customized patient medication package or patient med-pak.

(b) A patient med-pak is a series of containers prepared by a pharmacist for a specific patient containing one or more prescribed solid oral dosage forms and designed or labeled to indicate the day and time, or period of time, when the contents within each container are to be taken.

(c) The pharmacist shall prepare a label for a patient med-pak that includes

(1) the name of the patient;

(2) the unique identification number for the patient med-pak itself and a separate unique identification number for each of the prescription drug orders for the drug products in the patient med-pak;

(3) the name, strength, physical description or identification, and total quantity of each drug product in the patient med-pak;

(4) the directions for use and cautionary statements, if any, contained in the prescription drug order for each drug product in the patient med-pak;

(5) any other information, statements, or warnings required or appropriate for any of the drug products in the patient med-pak;

(6) the name of the prescribing practitioner of each drug product in the patient med-pak;

(7) the date of preparation of the patient med-pak and the expiration date assigned to the patient med-pak; the expiration date may not be more than 60 days from the date of preparation of the patient med-pak;

(8) the name, address, and telephone number of the pharmacy; and

(9) the initials of the dispensing pharmacist.

(d) If the patient med-pak allows for the removal or separation of the intact containers from the patient med-pak, the pharmacist shall label each individual container of the patient med-pak to identify each of the drug products contained in the patient med-pak.

(e) When preparing a patient med-pak, the dispensing pharmacist shall take into account any applicable compendium requirements or guidelines and the physical and chemical compatibility of the dosage forms placed within each container in the med-pak and any therapeutic incompatibilities that may attend the simultaneous administration of the drugs.

(f) In addition to any individual prescription filing requirements, the pharmacist shall make and file a record of each patient med-pak. Each record must contain

(1) the name and address of the patient;

(2) a unique identification number for the patient med-pak itself and a separate, unique, identification number for each of the prescription drug orders for each drug product contained in the patient med-pak;

(3) information identifying or describing the design, characteristics, or specifications of the patient med-pak that is sufficient to prepare an identical patient med-pak for the patient;

(4) the date of preparation of the patient med-pak and the expiration date assigned;

(5) any special labeling instructions; and

(6) the name or initials of the pharmacist who prepared the patient med-pak.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.530. RETURN OR EXCHANGE OF DRUGS. (a) A pharmacy or pharmacist may accept a drug for return or exchange after the drug has been taken from the premises where the drug was sold, distributed, or dispensed if

(1) the prescription was dispensed in a manner inconsistent with the original prescription drug order; or the medication was recalled by the manufacturer or the United States Food and Drug Administration; and

(2) the drug is segregated from the normal pharmacy inventory and may not be dispensed.

(b) A pharmacy serving an institutional facility may accept for return or reuse unit dose packages or full or partial multiple dose medication cards if

(1) the pharmacist can readily determine that there has been no entry or attempt at entry to the unit dose package or blister card;

(2) in the pharmacist's professional judgment, the unit dose package or multiple dose medication card meets the standards of the United States Pharmacopoeia (1995 revision) for storage conditions, including temperature, light sensitivity, and chemical and physical stability;

(3) the drug has not come into the physical possession of the person for whom it was prescribed, and control of the drug is known to the pharmacist to have been the responsibility of a person or persons licensed to prescribe, dispense, or administer drugs; and

(4) the drug labeling or packaging has not been altered or defaced, and the identity of the drug, its strength, lot number, and expiration date are retrievable.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: A copy of the United States Pharmacopoeia may be obtained from the United States Pharmacopoeial Convention, Inc., P.O. Box 560, Williston, VT 05495.

12 AAC 52.540. NOTIFICATION OF THEFT OR SIGNIFICANT LOSS. If a pharmacy is required under 21 U.S.C. 801 - 904 (Controlled Substances Act) to complete DEA Form 106, "Report of Theft or Loss of Controlled Substances," the pharmacist-in-charge shall also send a copy of the completed form to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157

12 AAC 52.550. ADVERTISING. A pharmacy may advertise prescription drug prices if the advertisement contains all of the following information:

(1) proprietary, trade, or generic name of the drug product;

(2) name of the manufacturer or distributor of the drug product;

(3) dosage form and strength of the drug product;

(4) price charged for a specific quantity of the drug product; and

(5) the hours that pharmaceutical services are available from the advertiser.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.560. DESTRUCTION AND DISPOSAL OF DRUGS. (a) A licensed pharmacist may destroy noncontrolled prescription drugs if the drugs are destroyed in a manner that makes the drugs unfit for human consumption.

(b) A drug that is a controlled substance shall be disposed of in accordance with federal statutes and regulations.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.570. DRUG REGIMEN REVIEW. (a) A pharmacist shall perform a drug regimen review, as defined in AS 08.80.480, for each prescription drug order.

(b) If a pharmacist identifies any of the items listed in AS 08.80.480 during the drug regimen review, the pharmacist shall avoid or resolve the problem by consulting with the prescribing practitioner, if necessary.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.580. DATA PROCESSING SYSTEMS. A pharmacy may use an automated data processing system to maintain the records required in AS 08.80 and this chapter if the system

(1) is capable of on-line retrieval of all information required in 12 AAC 52.460, 12 AAC 52.470, and 21 C.F.R. 1306.22, as amended as of February 6, 1997;

(2) is capable of producing an audit trail printout for all dispensing of any specified strength and dosage form of a drug; and

(3) has adequate safeguards to prevent loss of data and reasonable security to prevent unauthorized access to, modification of, or manipulation of patient records.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.585. MANDATORY PATIENT COUNSELING. (a) Before dispensing a prescription for the first time for a new patient of the pharmacy, a prescription for a new medication for an existing patient of the pharmacy, or a change in the dose, strength, route of administration, or directions for use of an existing prescription previously dispensed for an existing patient of the pharmacy, the pharmacist or pharmacy intern providing prescription services shall personally counsel each patient or the patient's agent on matters considered significant in the pharmacist's professional judgment. The counseling may include

(1) the name and description of the prescribed drug;
(2) the dosage and the dosage form;
(3) the method and route of administration;
(4) the duration of the prescribed drug therapy;
(5) any special directions and precautions for preparation, administration, and use by the patient that the pharmacist determines are necessary;
(6) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, how to avoid them, and what actions should be taken if they occur;
(7) patient techniques for self-monitoring of the drug therapy;
(8) proper storage;
(9) prescription refill information; and
(10) the action to be taken in the event of a missed dose.

(b) A pharmacist shall counsel the patient or the patient's agent face-to-face. If face-to-face counseling is not possible, a pharmacist shall make a reasonable effort to provide the counseling by use of a telephone, two-way radio, or in writing. In place of a pharmacist's own written information regarding a prescribed drug, the pharmacist may use abstracts of the Patient United States Pharmacopoeia Drug Information or comparable information.

(c) This section does not apply to a pharmacist who dispenses drugs for inpatient use in a hospital or other institution if the drug is to be administered by a nurse or other appropriate health care provider.

(d) This section does not require a pharmacist to provide patient counseling when a patient or the patient's caregiver refuses the counseling.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

12 AAC 52.590. PREPACKAGING OF DRUGS. For the purpose of supplying drugs to a prescribing practitioner, drugs shall be prepackaged in child-resistant containers under the direct supervision of a pharmacist and bear a label that contains

(1) the name, address, and telephone number of the pharmacy;
(2) the name, strength, and quantity of the drug;
(3) the lot number and expiration date of the drug, if not already contained on the unit-of-use or drug packaging;
(4) cautionary information required for patient safety and information; and
(5) the initials of the pharmacist.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.480

ARTICLE 6.
WHOLESALE DRUG DISTRIBUTORS AND FACILITIES.

Section

610. Wholesale drug distributor license
620. Wholesale drug facilities
625. Personnel requirements; grounds for denial or other disciplinary action
630. Drug storage
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12 AAC 52.610. WHOLESALE DRUG DISTRIBUTOR LICENSE. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a wholesale drug distributor license. An applicant who does not meet the requirements of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive a wholesale drug distributor license will not

be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a wholesale drug distributor license.

(b) The board will issue a wholesale drug distributor license to an applicant who

(1) submits a completed, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the wholesale drug facility;

(4) provides the name and the resume of the facility manager who will manage the wholesale distribution of drugs and the wholesale drug facility;

(5) submits

(A) a completed self-inspection of the premises questionnaire on a form provided by the department; or

(B) a completed Verification Accredited Wholesale Distributors (VAWD) inspection report;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits a copy of a current valid license, permit, or registration to conduct operations in the jurisdiction in which it is located, if the applicant is a wholesale drug distributor located outside of this state.

(c) An applicant for a wholesale drug distributor license that will be distributing controlled substances shall

(1) meet the requirements of (b) of this section; and

(2) be registered with the DEA.

(d) Within 30 days after a change in location, ownership, or facility manager, the new facility manager must

(1) submit the completed change of facility manager form provided by the department;

(2) submit the applicable fees established in 12 AAC 02.105(3); and

(3) meet the requirements of (b)(4) and (6) of this section.

(e) When a wholesale drug distributor ceases operations, the facility manager of the wholesale drug distributor shall notify the board on a form provided by the department of the cessation of operations; the form must be submitted within 10 days after the cessation of operations.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.620. WHOLESALE DRUG FACILITIES. (a) A wholesale drug facility in which drugs are stored, repacked, or sold to persons, businesses, or government agencies that may legally purchase drugs must

(1) have storage areas that ensure proper lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(2) be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations;

(3) be equipped with an alarm system to detect entry into the wholesale drug facility after business hours;

(4) meet all applicable federal, state, and local building standards;

(5) be secure from unauthorized entry from outside the facility, including having exterior lighting along the outside perimeter of the facility;

(6) restrict entry into areas inside the facility where drugs are stored; entry must be open to authorized personnel only;

(7) have a quarantine area for storage of drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in a secondary container that has been opened or the seal of which has been broken;

(8) be maintained in a clean and orderly condition; and

(9) be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) A wholesale drug facility must develop internal security policies, including protection of computer records, to provide reasonable protection against theft or diversion of drugs by personnel.

(c) A wholesale drug facility may not be located in a residence.

(d) A wholesale drug distributor facility seeking to ship into or distribute prescription drugs in this state must first verify that the purchaser of the prescription drugs holds a valid license under AS 08.80.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.625. PERSONNEL REQUIREMENTS; GROUNDS FOR DENIAL OR OTHER DISCIPLINARY ACTION. (a) A wholesale drug distributor shall maintain a roster of all officers, directors, and managers responsible for wholesale drug distribution, storage, and handling. The roster shall include a description of each person's duties and a summary of the person's experience.

(b) The board will not approve an application for a wholesale drug distributor license unless the designated facility manager in charge of the drug facility documents having a basic knowledge of federal and state laws related to the wholesale distribution of drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159 AS 08.80.480

12 AAC 52.630. DRUG STORAGE. (a) A wholesale drug distributor shall ensure that all drugs are stored at appropriate temperatures in accordance with label requirements to help ensure that the identity, strength, quality, and purity of the products are not affected.

(b) A wholesale drug distributor shall ensure that a separate quarantine storage area is provided for drugs that are deteriorated, outdated, damaged, misbranded, adulterated, or are in a secondary container that has been opened or the seal of which has been broken.

(c) A wholesale drug distributor shall ensure that appropriate manual, electromechanical, or electronic temperature and humidity recording equipment or handwritten logs are used to document how drugs have been stored.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.640. WRITTEN POLICIES AND PROCEDURES. A wholesale drug distributor shall prepare and follow a written procedure to

(1) handle crisis situations that affect the security or operation of the wholesale drugs facility, including fire, flood, earthquake or other natural disasters, and situations of local, state, or national emergency;

(2) identify, record, report to the board, and correct any error found in an inventory;

(3) ensure that any outdated drug or any drug with an expiration date that, in the wholesale drug distributor's view, does not allow sufficient time for repacking or resale, is segregated from other stock, is documented as a drug that has a characteristic described in this paragraph and is prepared for timely return to the manufacturer or is destroyed;

(4) ensure that the wholesale drug distributor exercises control over the shipping and receiving of all drugs within the wholesale drug distribution operation;

(5) ensure the proper handling and disposal of returned drugs;

(6) ensure that the oldest approved stock of a drug is distributed first and that any deviation from this requirement is only temporary;

(7) ensure the proper handling of a drug recall and a replacement of a drug in accordance with 12 AAC 52.670.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.645. EXAMINATION OF DRUG SHIPMENTS. (a) A wholesale drug distributor shall ensure that upon receipt of a drug shipment, each outside shipping container is visually examined for identity and damage in order to reduce the acceptance of drugs that are contaminated or unfit for distribution.

(b) A wholesale drug distributor shall ensure that each outgoing shipment of drugs is inspected for identity of the contents and the integrity of the shipping container in order to ensure that the drugs to be shipped were not damaged in storage, held under improper conditions, or likely to receive damage in shipment.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.650. RECORDS AND INVENTORIES. (a) A wholesale drug distributor shall establish and maintain records and inventories of all transactions regarding the receipt, distribution, or disposition of a drug. The records must include the following information:

(1) the source of the drug, including the name and principal address of the seller or transferor and the address of the location from which the drug was shipped;

(2) the identity and quantity of the drug received, distributed, or disposed of; and

(3) the date of receipt and of distribution or other disposition.

(b) The records and inventories required by this section must be made available at a central location for inspection within two working days after a request by an authorized inspector. The records and inventories required by this section must be kept for a period of two years after disposition of the drug.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.660. RETURNED, DAMAGED, AND OUTDATED DRUGS. (a) A wholesale drug distributor shall ensure that a drug that is outdated, damaged, deteriorated, misbranded, or adulterated is quarantined and physically separated from other drugs until it is either destroyed or returned to the supplier.

(b) A wholesale drug distributor shall ensure that a drug that has a secondary container that has been opened or used is identified as such, and is quarantined and physically separated from other drugs until the drug is either destroyed or returned to the supplier.

(c) A wholesale drug distributor shall ensure that if the conditions under which a drug has been returned, shipped, or stored cast doubt on the drug's safety, identity, strength, quality, or purity, the drug is destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.670. DRUG RECALLS. A wholesale drug distributor shall prepare and follow a written policy for handling the recall of a drug due to

(1) a voluntary action on the part of the manufacturer;

(2) an order of the Food and Drug Administration, or of any other federal, state, or local government agency; or

(3) the replacement of an existing drug with an improved drug or new package design.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.680. INSPECTIONS. A wholesale drug distributor shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect that distributor's facilities and delivery vehicles at reasonable times and in a reasonable manner, and to inspect that distributor's records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.685. PROHIBITIONS AGAINST DIRECT DISTRIBUTION. A wholesale drug distributor may not distribute a drug or preparation directly to a consumer or patient.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.261
AS 08.80.030 AS 08.80.159

12 AAC 52.690. SALVAGE AND REPROCESSING. A wholesale drug distributor is subject to the provisions of all applicable federal and state statutes and regulations and local ordinances that relate to drug salvaging or reprocessing, including 21 C.F.R. Parts 207, 210, and 211, as amended as of February 6, 1997.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.159

12 AAC 52.695. PROVISIONS NOT APPLICABLE. The following activities do not constitute wholesale distribution of prescription drugs for which a wholesale drug distributor license is required by 12 AAC 52.610 – 12 AAC 52.690:

(1) intracompany sales, defined as any transaction or transfer between any division, subsidiary, parent, and an affiliated or related company under the common ownership and control of a corporate entity;

(2) the purchase or acquisition, by a hospital or other health care entity that is a member of a group purchasing organization, of a drug, for its own use, from the group purchasing organization or from another hospital or health care entity that is a member of the group purchasing organization;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in 26 U.S.C. 501(c)(3) (Internal Revenue Code of 1954), as amended as of February 6, 1997, to a nonprofit affiliate of the organization to the extent otherwise permitted by the law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control; for purposes of this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise;

(5) any of the following transfers of a drug, if the gross dollar value of the transfer does not exceed five percent of the total prescription drug sales revenue of either the transferor or transferee during any 12-consecutive-month period:

(A) the sale of a drug by a retail pharmacy to another retail pharmacy or to a practitioner, or the offer by a retail pharmacy to sell a drug to another retail pharmacy or to a practitioner;

(B) the purchase of a drug by a retail pharmacy or by a practitioner from another retail pharmacy, or the offer by a retail pharmacy or by a practitioner to purchase a drug from another retail pharmacy;

(C) the trade of a drug by a retail pharmacy with another retail pharmacy, or the offer by a retail pharmacy to trade a drug with another retail pharmacy;

(6) the sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug, under a prescription;

(7) the distribution of drug samples by manufacturers' representatives or distributors' representatives; or

(8) the sale, purchase, or trade of blood and blood components intended for transfusion.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.159

AS 08.80.030

12 AAC 52.696. OUTSOURCING FACILITIES. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for an outsourcing facility license. An applicant who does not meet the requirements of (b) of this section or whose responses on the form for application do not clearly show that the applicant is qualified to receive an outsourcing facility license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for an outsourcing facility license.

(b) The board will issue an outsourcing facility license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and resumes of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department;

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety; and

(7) submits the results of the most recent Good Manufacturing Practice (GMP) inspection by the United States Food and Drug Administration.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department.

(d) The facility manager of an outsourcing facility that has changed its name or physical address must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(e) A new owner of an outsourcing facility must apply for a new and separate outsourcing facility license in accordance with (b) of this section.

(f) When an outsourcing facility ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the outsourcing facility ceased operations; and

(2) arrangement for the records of the outsourcing facility to be retained for two years.

(g) Outsourcing facility personnel shall permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

(h) The outsourcing facility must be registered as an outsourcing facility with the United States Food and Drug Administration under Sec. 503b, P.L. 113 – 54 (Drug Supply Chain Security Act).

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

12 AAC 52.697. THIRD-PARTY LOGISTICS PROVIDERS. (a) An applicant must meet the requirements set out in (b) of this section to demonstrate the necessary qualifications for a third-party logistics providers license. An applicant who does not meet the requirements on the checklist or whose responses on the form for application do not clearly show that the applicant is qualified to receive a third-party logistics provider license will not be issued a license unless the board reviews the application and determines that the applicant meets the qualifications in this section for a third-party logistics provider license.

(b) The board will issue a third-party logistics provider license to an applicant who

(1) submits a complete, notarized application on a form provided by the department;

(2) pays the fees required in 12 AAC 02.310;

(3) provides a list of the names and résumés of officers, directors, or primary stockholders responsible for the facility;

(4) provides the name and the resume of the designated facility manager;

(5) submits a completed self-inspection of the premises questionnaire on a form provided by the department; and

(6) submits completed fingerprint cards of the facility manager for evaluation and investigation by the Department of Public Safety.

(c) Within 10 days after a change in facility manager, the new facility manager must meet the requirements of (b) of this section and submit the change on a form provided by the department. The outgoing facility manager must submit a change on a separate form provided by the department

(d) The facility manager of a third-party logistics provider that has changed its name or physical address must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(e) A new owner of third-party logistics provider must apply for a new and separate third-party logistics provider license in accordance with (b) of this section.

(f) When a third-party logistics provider ceases operations, the facility manager must submit to the board a written notice of the cessation of operations. The written notice must be submitted within 10 days after the cessation of operations and include

(1) the date the third-party logistics provider ceased operations; and

(2) arrangement for the records of the third-party logistics provider to be retained for two years.

(g) A third-party logistics provider must permit an authorized inspector or law enforcement official, who shows proper identification, to enter and inspect the facility and delivery vehicles at reasonable times and in a reasonable manner, and to inspect the facility records and written operating procedures.

Authority: AS 08.80.005 AS 08.80.159 AS 08.80.480
AS 08.80.030

ARTICLE 7.
INSTITUTIONAL PHARMACIES.

Section

700. (Repealed)
710. Absence of a pharmacist from an institutional pharmacy
720. Emergency room outpatient medications
730. Drug distribution and control

12 AAC 52.700. INSTITUTIONAL PHARMACIES. Repealed 2/26/2000.

12 AAC 52.710. ABSENCE OF A PHARMACIST FROM AN INSTITUTIONAL PHARMACY. (a) When an institutional pharmacy will be unattended by a pharmacist, the pharmacist-in-charge shall arrange in advance for providing drugs for use within the institutional facility.

(b) When an institutional pharmacy is closed and a drug is required to treat a patient's immediate need and is not available from the drug stock outside of the pharmacy, a person designated by the pharmacist-in-charge and licensed to handle drugs may obtain the drug from the institutional pharmacy. The pharmacist-in-charge is responsible

(1) to record on a suitable form the removal of any drug from the institutional pharmacy by the person designated; the record must show the

(A) patient's name and room number;

(B) name, strength, and amount of the drug;

(C) date and time of removal; and

(D) initials or signature of the person designated who removed the drug from the pharmacy;

(2) when the pharmacy reopens or as soon as is practical, to check the stock container or similar unit dose package of the drug removed; and

(3) to ensure that the quantity of drugs that were removed is only the quantity necessary to sustain the patient until the pharmacy reopens.

(c) If an institutional pharmacy is open and the pharmacist is absent from the pharmacy, but present in the institutional facility, a pharmacy technician may continue to prepare and process drug prescriptions. However, drugs may not be dispensed until the pharmacist has verified the finished prescription product.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.720. EMERGENCY ROOM OUTPATIENT MEDICATIONS. (a) The pharmacist-in-charge of an institutional pharmacy, in cooperation with the appropriate committee of the institutional facility's medical staff, shall prepare a list of prescription drugs that may be delivered to outpatients receiving emergency treatment and shall determine appropriate quantities for unit-of-use packaging and prepackaging of the prescription drug.

(b) A licensed health care provider on emergency room staff may deliver the medications identified on the list of prescription drugs prepared under (a) of this section to a patient receiving emergency outpatient treatment if

(1) the drug is ordered by an authorized prescribing practitioner either in writing or verbally; a verbal order must be transcribed into writing on the patient's record;

(2) the medication is prepackaged in a child-resistant container under the direct supervision of a pharmacist;

(3) the medication bears a label that contains the

(A) name, address, and telephone number of the institutional facility;

(B) name, strength, and quantity of the drug;

(C) cautionary information required for patient safety and information;

(D) lot number and expiration date if not already contained on the unit-of-use packaging or prepackaging; and

(E) initials of the pharmacist;

(4) no more than one prepackaged container of a drug is delivered to a patient unless more than one package is required to sustain the patient until a retail pharmacist is on duty in the community; however, the amount of the controlled substance delivered may not exceed a 72 hour supply; and

(5) labeling of the container is completed by the licensed health care provider before the container is presented to the patient; the container label must include the

(A) name of the patient;
(B) directions for use by the patient;
(C) date of delivery;
(D) identifying number unique to the patient;
(E) name of the prescribing practitioner; and
(F) initials of the licensed health care provider delivering the prepackaged medication.

(c) Prepackaged medications shall be kept in a secure place within the emergency room.

(d) Following delivery of the prepackaged medication to the patient, the licensed health care provider shall document the quantity issued and initial the patient record containing the prescribing practitioner's order.

(e) This section does not apply to the administration of a single dose to a patient.

(f) In this section, "licensed health care provider" means a physician, physician assistant, or mobile intensive care paramedic licensed under AS 08.64; a dentist licensed under AS 08.36; or a nurse licensed under AS 08.68.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.730. DRUG DISTRIBUTION AND CONTROL. (a) The pharmacist-in-charge of an institutional pharmacy is responsible for the storage, preparation, distribution, and control of the institutional facility's drug supply and for ensuring that these activities are carried out in conformance with established policies, procedures, and accepted standards.

(b) The pharmacist-in-charge of an institutional pharmacy shall establish written procedures for the distribution and control of drugs and for the provision of pharmacy service. The procedures must be consistent with 12 AAC 52.710 and 12 AAC 52.720. The pharmacist-in-charge shall make an annual updated copy of the policies and procedures available for inspection by the board.

(c) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter shall provide drug information to the staff and practitioners of the institutional facility.

(d) Persons employed at an institutional pharmacy who are licensed under AS 08.80 and this chapter may assist in the planning of and participate in the institutional facility's education and staff development programs relating to drugs.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

ARTICLE 8.
DRUG ROOMS AND FACILITIES WITHOUT A PHARMACY.

Section

800. Drug room license
810. Pharmacist required
820. Responsibilities of the consultant pharmacist
830. Emergency drug kits
840. First dose kits
850. Emergency distribution

12 AAC 52.800. DRUG ROOM LICENSE. (a) An institutional facility that does not maintain a pharmacy but prepares and administers prescription drugs from bulk supplies for patients receiving treatment within the facility must be licensed by the board as a drug room under 12 AAC 52.010 and 12 AAC 52.020.

(b) An institutional facility that does not maintain a pharmacy but stores and administers prescription drugs that are labeled and dispensed for specific patients by a pharmacy does not require a drug room or pharmacy license.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.810. PHARMACIST REQUIRED. An institutional facility described in 12 AAC 52.800(a) must continuously employ a pharmacist or have a written agreement with a pharmacy or pharmacist to provide consultant pharmacist services.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.820. RESPONSIBILITIES OF THE CONSULTANT PHARMACIST. A pharmacist who, under 12 AAC 52.810, provides consultant pharmacy services shall

(1) provide evaluations and recommendations concerning drug distribution, control, and use;

(2) complete on-site reviews to ensure that drug handling and use procedures conform to AS 08.80, this chapter, and recognized standards of practice;

(3) provide drug information to facility staff and physicians;

(4) plan and participate in the facility's staff development program relating to drug distribution, control, and use;

(5) assist in establishing policies and procedures to control the distribution and administration of drugs; and

(6) document pharmacy services that are provided and maintain the documentation for a period of at least two years.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.830. EMERGENCY DRUG KITS. (a) An institutional facility described in 12 AAC 52.800(b) may have a limited supply of drugs provided by a pharmacist licensed under this chapter and AS 08.80 in emergency drug kits on-site. An emergency drug kit is for use by personnel authorized to administer the drugs to patients receiving treatment within the institutional facility.

(b) The pharmacist who provides or supplies drugs in emergency drug kits shall cooperate with the prescribing practitioners on staff at the institutional facility to determine the identity and quantity of the drugs to be included in the emergency drug kits.

(c) An emergency drug kit must

(1) only contain drugs that are not available from any other source in sufficient time to prevent risk of harm to patients;

(2) only contain drugs that are provided and sealed by a pharmacist;

(3) be stored in a secured area to prevent unauthorized access;

(4) be labeled on the exterior to indicate it is for use only in emergencies as described in this section; and

(5) have a list of the kit's contents posted on or near the kit.

(d) Drugs may be removed from an emergency drug kit only under a valid order from a prescribing practitioner.

(e) When the supplying pharmacist is notified that an emergency drug kit has been opened, the supplying pharmacist shall restock the kit within a reasonable time, not to exceed seven days.

(f) The supplying pharmacist shall label the exterior of an emergency drug kit to indicate the expiration date of the kit's contents. The expiration date of an emergency drug kit is the earliest expiration date of any drug supplied in the kit. When an emergency drug kit expires, the supplying pharmacist shall replace any expired drugs in the kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

12 AAC 52.840. FIRST DOSE KITS. (a) In addition to the emergency drug kit described in 12 AAC 52.830, an institutional facility described in 12 AAC 52.800 may maintain a first dose kit for the initiation of nonemergency drug therapy to a patient receiving treatment within the institutional facility if the necessary drug is not available from a pharmacy in time to prevent risk of harm to a patient.

(b) The dispensing or consultant pharmacy for the institutional facility and the medical staff of the institutional facility are responsible for the proper storage, security, and accountability of the first dose kit.

(c) The staff of the dispensing or consultant pharmacy for the institutional facility shall determine jointly with the medical staff of the institutional facility the content and quantity of drugs to be included in the first dose kit.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.390
AS 08.80.030

12 AAC 52.850. EMERGENCY DISTRIBUTION. In an emergency, if a drug is not otherwise available, a drug room may distribute the drug from bulk supplies to a practitioner or a pharmacist for use by a patient outside the facility, under a prescription, until the drug can be otherwise obtained.

Authority: AS 08.80.005 AS 08.80.157 AS 08.80.480
AS 08.80.030 AS 08.80.390

ARTICLE 9.
CONTROLLED SUBSTANCE PRESCRIPTION DATABASE.

Section

855. Registration with the prescription drug monitoring program controlled substance prescription database

860. Access to and conditions for use of the prescription drug monitoring program database

865. Reporting and reviewing PDMP information
870. Waiver of electronic submission requirement by pharmacist or practitioner
875. Solicited requests for information from non-registered persons
880. Reports
885. Purged database records
890. Grounds for discipline
895. Correcting information in database

12 AAC 52.855. REGISTRATION WITH THE PRESCRIPTION DRUG MONITORING PROGRAM CONTROLLED SUBSTANCE PRESCRIPTION DATABASE. (a) A licensed pharmacist shall register with the prescription drug monitoring program's controlled substance prescription database (PDMP) before dispensing a schedule II, III, or IV controlled substance under federal law.

(b) Before dispensing, prescribing, or administering a schedule II, III, or IV controlled substance under federal law, a pharmacist or practitioner required to register with the PDMP must

(1) register online on the PDMP website; and

(2) pay the fee established in 12 AAC 02.107.

(c) After completing the registration requirements, a pharmacist or practitioner required to register with the PDMP will be issued a user account, login name, and password by the department.

(d) A pharmacist or practitioner required to register with the PDMP must access information in the PDMP using the user account, login name, and password issued by the department.

(e) A pharmacist or practitioner required to register with the PDMP may access information in the PDMP using another registrant's credentials only as authorized by a contract executed by the department for the purposes of AS 47.05.270.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.860. ACCESS TO AND CONDITIONS FOR USE OF THE PRESCRIPTION DRUG MONITORING PROGRAM DATABASE. (a) Access to the PDMP is limited as described in AS 17.30.200(d).

(b) For the purposes in AS 17.30.200(d)(1) of an inquiry under a search warrant, subpoena, or order issued by an administrative law judge or a court,

(1) "personnel of the board" means employees of the Department of Commerce, Community, and Economic Development assigned to the Board of Pharmacy; and

(2) "personnel of another board or agency" means an employee of this state who is assigned to a board or agency that requires a practitioner to register with the PDMP.

(c) For the purposes of AS 17.30.200(d)(2), "authorized board personnel or contractors" means:

(1) employees of the Department of Commerce, Community, and Economic Development, assigned to the Board of Pharmacy, and providing PDMP data storage or data management services; or

(2) employees of a contractor with this state who are providing PDMP data storage or data management services.

(d) For the purposes of AS 17.30.200(d)(3) and (4), a licensed practitioner or licensed or registered pharmacist authorizing an agent or employee to access the PDMP is responsible for maintaining and terminating the agent or employee's access to the PDMP.

(e) For the purposes of AS 17.30.200(d)(8) and (10), "authorized employee of the Department of Health and Social Services" means an employee of the Department of Health and Social Services (DHSS) for whom that department's commissioner or commissioner's official designee has requested access in writing to the board before the release of information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.865. REPORTING AND REVIEWING PDMP INFORMATION. (a) Unless excused from reporting under AS 17.30.200(t), a pharmacist must submit information required under AS 17.30.200(b), if the pharmacist-in-charge is not present.

(b) Unless excused from reporting under AS 17.30.200(t), a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP daily as of the previous submission date.

(c) The time computation under 12 AAC 02.920(b) applies to a submission of information under AS 17.30.200(b) and this section.

(d) For the purposes of AS 17.30.200(b)(1), "other appropriate identifier" and for the purposes of AS 17.30.200(b)(8), "other appropriate identifying information" mean the state-issued license number of the prescribing practitioner and state-issued license number of the dispensing pharmacist or practitioner.

(e) Not later than 72 hours after discovering an error in information submitted under AS 17.30.200(b), a pharmacist or practitioner required to submit the information under AS 17.30.200(b) must submit information correcting the error to the PDMP administrator. The time computation under 12 AAC 02.920(b) applies to a submission of information correcting an error in information submitted under AS 17.30.200(b).

(f) Unless excused from reporting under AS 17.30.200(t), or a waiver is granted under 12 AAC 52.870, a pharmacist or practitioner required to submit information under AS 17.30.200(b) must submit the information to the PDMP electronically through the website provided by the board.

(g) Unless excused from reviewing the PDMP under AS 17.30.200(k)(4)(A) – (B), a practitioner, but not a pharmacist, must review the information in the PDMP to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.870. WAIVER OF ELECTRONIC SUBMISSION REQUIREMENT BY PHARMACIST OR PRACTITIONER. (a) The department shall waive the electronic submission requirements of 12 AAC 52.865(f) for good cause. The pharmacist or practitioner requesting the waiver is responsible for establishing the basis for the requested waiver under this section.

(b) To establish good cause for purposes of this section, a pharmacist or practitioner must submit an application and sworn statement showing that

(1) a natural disaster or other emergency beyond the control of the pharmacist or practitioner prevents the pharmacist or practitioner from complying with 12 AAC 52.865(f);

(2) the pharmacist or practitioner will only dispense controlled substances as part of a controlled research project approved by an accredited institution of higher education or under the supervision of a government agency;

(3) the pharmacist's or practitioner's business is located in an area that lacks access to the telecommunication services needed to comply with 12 AAC 52.865(f); or

(4) the pharmacist or practitioner will suffer financial hardship if required to acquire the technology necessary to comply with 12 AAC 52.865(f).

(c) The department may not grant a waiver under this section unless the pharmacist or practitioner first agrees in writing that, if the waiver is granted, the pharmacist or practitioner will satisfy the reporting requirements of AS 17.30.200(b) by submitting the required information by United States mail to the board on at least a daily basis using a form approved by the board.

(d) A request for a waiver under this section must be in writing using an application form provided by the board and sent to the board.

(e) The department's grant or denial of a waiver request constitutes a final agency action unless, no later than 30 days after the department issues notice of the grant or denial, the pharmacist or practitioner files a written notice of appeal with the board.

(f) A waiver granted under this section expires at the end of the year in which it is granted.

(g) A pharmacist or practitioner must inform the board within 30 days if the basis for the waiver of electronic reporting no longer exists.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.875. SOLICITED REQUESTS FOR INFORMATION FROM NON-REGISTERED PERSONS. (a) A patient authorized under AS 17.30.200(d)(6) to receive information from the controlled substance prescription database, the patient's authorized agent, or in the case of a unemancipated minor unable to give consent for medical services under AS 25.20.025(a), the minor's parent or legal guardian, may request profile information from the controlled substance prescription database concerning the patient if the person requesting the information

(1) submits the request on a form provided by the board;

(2) pays a $10 fee; and

(3) does one of the following:

(A) if a patient, presents to the department, in person, government-issued photographic identification confirming the patient's identity as the same person on whom profile information is sought;

(B) if a patient, submits a signed and notarized request

(i) verifying that the patient is the same person on whom profile information is sought; and

(ii) providing the patient's full name, address, and date of birth;

(C) presents a valid power of attorney concerning the patient, or presents

(i) verification that the person requesting the information is the parent, legal guardian, or legal administrator of a minor, incapacitated person, or deceased person on whom profile information is sought; and

(ii) if the person is a parent or legal guardian of a patient who is a minor, verification that the patient is not an emancipated minor legally able to consent to medical treatment under AS 25.20.025.

(b) Profile information may be

(1) disseminated in person; or

(2) mailed certified mail, return receipt requested, no later than five days after the date that the department receives a request that meets the requirements of this section.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.880. REPORTS. (a) The board will maintain a register for patient profile requests solicited under 12 AAC 52.875. The register includes the following information:

(1) the date on which the request was received;
(2) the name of the patient and the patient's date of birth;
(3) the name, title, and address of the individual requesting the profile;
(4) the date on which the information was disseminated, mailed, or sent by facsimile transmission.

(b) The register and the information in it are confidential and may only be accessed subject to the restrictions set out in AS 17.30.200(d) and 12 AAC 52.855 - 12 AAC 52.890.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.885. PURGED DATABASE RECORDS. The following information will be purged from the PDMP database after two years have elapsed from the date the prescription was dispensed:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;
(2) the date of the prescription;
(3) the date the prescription was filled and the method of payment;
(4) the name, address, and date of birth of the person for whom the prescription was written;
(5) the name and national drug code of the controlled substance;
(6) the quantity and strength of the controlled substance dispensed;
(7) the name of the drug outlet dispensing the controlled substance; and
(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.890. GROUNDS FOR DISCIPLINE. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a pharmacist is grounds for the imposition of disciplinary sanctions under AS 08.01.075 and AS 08.80.261. A violation of 12 AAC 52.855 – 12 AAC 52.885 by a practitioner not licensed by this board shall be reported to the practitioner's licensing board.

Authority: AS 08.80.005 AS 08.80.030 AS 17.30.200

12 AAC 52.895. CORRECTING INFORMATION IN DATABASE. (a) To request a correction under AS 17.30.200(k)(2) to information in the controlled substance prescription database concerning a person, that person must submit to the board

(1) on a form or in a format prescribed by the board,
  (A) a description of the information asserted to be incorrect, and the correction requested;
  (B) the mailing and physical address and telephone number of the requester; and
  (C) a signed, sworn statement attesting to the truth of the corrected information;
(2) documentation to support the correction requested; and
(3) proof of the requester's identity.

(b) If the board determines that it

(1) has sufficient information to make a determination, the board will
  (A) notify the requester that the request is granted; or
  (B) issue a written denial of the request, if the board determines that the information for which a correction was requested is accurate and complete; in the denial, the board will notify the requester that the requester may request, in accordance with (c) of this section, an administrative hearing to contest the denial;
(2) lacks sufficient information to grant or deny the request, the board
  (A) will request additional information from the requester; and
  (B) will not act on the request until after the additional information is received.

(c) If the board receives, no later than 30 days after it issues a denial under (b)(1)(B) of this section, a written request for an administrative hearing, the board will conduct an administrative hearing of the denial through the Office of Administrative Hearings in accordance with AS 44.62 (Administrative Procedure Act) and AS 44.64. If the board does not receive a request, the denial is a final administrative decision for purposes of judicial review.

Authority: AS 08.80.005 AS 08.80.050 AS 17.30.020
AS 08.80.030

ARTICLE 10.
DISCIPLINARY GUIDELINES.

Section

900. Purpose of disciplinary guidelines
910. Violations
920. Disciplinary guidelines

925. Grounds for denial or discipline for criminal history
930. Terms of probation
940. Use of alcohol or controlled substances
950. Probation terms for professional incompetence
960. Mental or physical disabilities
970. Reinstatement of a suspended license
980. Reinstatement of a revoked license

12 AAC 52.900. PURPOSE OF DISCIPLINARY GUIDELINES. The disciplinary guidelines in 12 AAC 52.900 - 12 AAC 52.980 are established to ensure the board's disciplinary policies are known and are administered consistently and fairly.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.910. VIOLATIONS. (a) A person who is licensed under AS 08.80 and this chapter who, after a hearing under AS 44.62 (Administrative Procedure Act), is found to have violated a provision of AS 08.80 or this chapter is subject to the disciplinary penalties listed in AS 08.01.075, including public notice of the violation and penalty in appropriate publications.

(b) Nothing in the guidelines set out in 12 AAC 52.920 prohibits the board from imposing greater or lesser penalties than those described in 12 AAC 52.920 or restricting the practice of a licensee depending upon the circumstances of a particular case.

Authority: AS 08.80.005 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.920. DISCIPLINARY GUIDELINES. (a) In addition to acts specified in AS 08.80 or elsewhere in this chapter, each of the following constitutes engaging in unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075:

(1) knowingly dispensing a drug under a forged, altered, or fraudulent prescription drug order;

(2) dispensing drugs to an individual or individuals in quantities, dosages, or for periods of time that grossly exceed standards of practice, approved labeling of the federal Food and Drug Administration, or the guidelines published in professional literature; this paragraph does not apply to prescriptions dispensed to persons with intractable pain or to a narcotic drug dependent person in accordance with the requirements of 21 C.F.R. 1306.07, as amended as of February 6, 1997;

(3) delivering or offering to deliver a prescription drug in violation of AS 08.80 or this chapter;

(4) acquiring, possessing, or attempting to possess prescription drugs in violation of AS 08.80, AS 11.71, or this chapter;

(5) distributing prescription drugs to a practitioner or a pharmacy not in the course of professional practice or in violation of AS 08.80 or this chapter;

(6) refusing or failing to keep, maintain, or furnish any record, notification, or information required in AS 08.80 or this chapter;

(7) refusing entry into a pharmacy for an inspection authorized by AS 08.80 or this chapter;

(8) making a false or fraudulent claim to a third party for reimbursement for pharmacy services;

(9) operating a pharmacy in an unsanitary manner;

(10) making a false or fraudulent claim concerning a drug;

(11) refilling a prescription drug order for a period of time in excess of one year from the date of issue of that prescription drug order;

(12) violating the provisions of a board order or memorandum of agreement;

(13) failing to provide information or providing false or fraudulent information on an application, notification, or other document required in AS 08.80 or this chapter;

(14) for the following licensees, failing to establish or maintain effective controls against the diversion or loss of prescription drugs or prescription drug records, or failing to ensure that prescription drugs are dispensed in compliance with state and federal laws and regulations:

(A) a pharmacist-in-charge of a pharmacy;

(B) a sole proprietor or individual owner of a pharmacy;

(C) a partner in the ownership of a pharmacy; or

(D) a managing officer of a corporation, association, or joint-stock company owning a pharmacy;

(15) failing to use reasonable knowledge, skills, or judgment in the practice of pharmacy;

(16) knowingly delegating a function, task, or responsibility that is part of the practice of pharmacy to a person who is not licensed to perform that function, task, or responsibility when the delegation is contrary to AS 08.80 or this chapter or the delegation involves a substantial harm or risk to a patient;

(17) failing to exercise adequate supervision over a person who is authorized to practice only under the supervision of a pharmacist;

(18) violating AS 08.80.315 dealing with the confidentiality of records;

(19) discriminating on the basis of race, religious creed, color, national origin, ancestry, or sex in the provision of a service that is part of the practice of pharmacy;

(20) offering, giving, soliciting, or receiving compensation for referral of a patient;

(21) violating AS 08.80.261(a)(3); or

(22) violating AS 17.30.200 or a regulation adopted under AS 08.80.030 or AS 17.30.200 dealing with the PDMP.

(b) The board will, in its discretion, revoke a license if the licensee

(1) commits a violation that is a second offense;

(2) violates the terms of probation from a previous offense;

(3) violates AS 08.80.261(a)(1) or (4);

(4) intentionally or negligently engages in conduct that results in a significant risk to the health or safety of a patient or injury to a patient;

(5) is professionally incompetent if the incompetence results in risk of injury to a patient.

(c) The board will, in its discretion, suspend a license for up to two years followed by probation of not less than two years if the licensee

(1) wilfully or repeatedly violates AS 08.80 or this chapter; or

(2) is professionally incompetent if the incompetence results in the public health, safety, or welfare being placed at risk.

(d) The board will review, on an individual basis, the need for revocation or limitation of a license of a licensee who practices or attempts to practice while afflicted with a physical or mental illness, deterioration, or disability that interferes with the individual's practice of pharmacy.

Authority: AS 08.01.075 AS 08.80.005 AS 08.80.030 AS 08.80.261 AS 08.80.315 AS 08.80.460 AS 17.30.200

12 AAC 52.925. GROUNDS FOR DENIAL OR DISCIPLINE FOR CRIMINAL HISTORY. (a) As used in AS 08.80.261 and this chapter, crimes that affect the applicant's or licensee's ability to practice competently and safely include

(1) murder;

(2) manslaughter;

(3) criminally negligent homicide;

(4) assault;

(5) sexual assault;

(6) sexual abuse of a minor;

(7) unlawful exploitation of a minor, including possession or distribution of child pornography;

(8) incest;

(9) indecent exposure;

(10) robbery;

(11) extortion;

(12) stalking;

(13) kidnapping;

(14) theft;

(15) burglary;

(16) forgery;

(17) endangering the welfare of a child;

(18) endangering the welfare of a vulnerable adult;

(19) unlawful distribution or possession for distribution of a controlled substance; for purposes of this paragraph, "controlled substance" has the meaning given in AS 11.71.900;

(20) reckless endangerment.

(b) Convictions of an offense in another jurisdiction with elements similar to an offense listed in (a) of this section affect the applicant's or licensee's ability to practice competently and safely.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261

12 AAC 52.930. TERMS OF PROBATION. The board will, in its, discretion, subject a licensee who is placed on probation to one or more of the following terms of probation, and to other relevant terms of probation, including those in 12 AAC 52.940 - 12 AAC 52.960:

(1) obey all laws pertaining to the practice of pharmacy in this state;

(2) fully comply with the probation program established by the board and cooperate with representatives of the board;

(3) notify the board in writing of the dates of departure and return if the licensee leaves the state to reside or practice pharmacy outside the state;

(4) report in person at meetings of the board or to its designated representatives during the period of probation, as directed by the board;

(5) submit written reports and verification of actions as required by the board during the period of probation;

(6) if employed in the practice of pharmacy at any time during the period of probation, have the employer submit to the board verification that the employer understands the conditions of probation;

(7) be employed as a pharmacist only in a setting in which full supervision is provided and not personally act as a supervisor.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.940. USE OF ALCOHOL OR CONTROLLED SUBSTANCES. (a) In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for the habitual abuse of alcohol or illegal use of controlled substances may also be subject to one or more of the following:

(1) physical and mental health examinations as determined by the board to evaluate the licensee's ability to perform the professional duties of a pharmacist;

(2) as determined by the board, participation until completion in an ongoing program of rehabilitative counseling, Alcoholics Anonymous, Narcotics Anonymous, or an impaired practitioner group that includes progress reports from the care provider when requested by the board;

(3) abstaining from the personal use of alcohol or controlled substances in any form except when lawfully prescribed by a practitioner licensed to practice in Alaska;

(4) submitting to tests and samples required for the detection of alcohol or controlled substances at the request of the board or the board's representative.

(b) Access to a controlled substance in the work setting will, in the board's discretion, be restricted.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.950. PROBATION TERMS FOR PROFESSIONAL INCOMPETENCE. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation after being found professionally incompetent may be subject to one or more of the following terms of probation:

(1) successful completion of an appropriate course or courses in pharmacy, as determined by the board, before the end of the probationary period; or

(2) participation in 15 contact hours of appropriate continuing education in pharmacy.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.960. MENTAL OR PHYSICAL DISABILITIES. In addition to one or more of the terms of probation set out in 12 AAC 52.930, a licensee placed on probation for practicing or attempting to practice pharmacy while afflicted with a physical or mental illness, deterioration, or disability that interferes with the licensee's performance of pharmacy may be subject to a physical or mental health examination to evaluate the licensee's ability to perform the professional duties of a pharmacist and if medically determined to be necessary, may be required to participate in and complete a recommended treatment program that includes written progress reports from the care provider when requested by the board.

Authority: AS 08.01.075 AS 08.80.261 AS 08.80.450
AS 08.80.030

12 AAC 52.970. REINSTATEMENT OF A SUSPENDED LICENSE. The board may reinstate a suspended license only if the requirements of the suspension order have been met.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

12 AAC 52.980. REINSTATEMENT OF A REVOKED LICENSE. (a) One year after revocation of a license, a licensee may apply to the board in writing for reinstatement of the license.

(b) The applicant for reinstatement shall appear before the board.

(c) The board will, in its discretion, impose restrictions upon the pharmacist or pharmacy when reinstating a license.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.261
AS 08.80.005

ARTICLE 11.
GENERAL PROVISIONS.

Section

985. Emergency preparedness
990. Display of license certificate
991. Disciplinary decision or conviction reporting requirement
992. Independent administration of vaccines and related emergency medications
993. Executive administrator
994. Independent dispensing of opioid overdose drugs by pharmacists
995. Definitions

12 AAC 52.985. EMERGENCY PREPAREDNESS. (a) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor that results in the inability to refill existing prescriptions, the board will cooperate with the state, borough, city, or town to assist in the provision of drugs, devices, and professional services to the public.

(b) If, as a consequence of a disaster or terrorist attack, a disaster emergency is declared by the governor of another state or territory, or a province of Canada which results in an individual being temporarily relocated to Alaska who is unable to refill an existing prescription, the board will assist in the provision of drugs, devices, and professional services to the relocated individual.

(c) Repealed 4/3/2020.

(d) Repealed 4/3/2020.

(e) To assist during an emergency, a pharmacist who is not licensed in this state may apply for emergency licensure in accordance with 12 AAC 52.110.

(f) During a disaster emergency declared by the governor of this state,

(1) a pharmacist or pharmacist intern may administer immunizations, in accordance with 12 AAC 52.992, without obtaining or maintaining a CPR certificate;

(2) the notice required under 12 AAC 52.150(a) need not be provided until 30 days after the date that the disaster emergency ends;

(3) an application under 12 AAC 52.070, 12 AAC 52.092, 12 AAC 52.095, 12 AAC 52.120, 12 AAC 52.423, 12 AAC 52.610, 12 AAC 52.696, and 12 AAC 52.697 does not need to be notarized.

Authority: AS 08.80.005 AS 08.80.030

12 AAC 52.990. DISPLAY OF LICENSE CERTIFICATE. A licensee shall conspicuously display, in the practice site, the licensee's current license certificate. Pending receipt of the current license certificate from the department, the licensee shall display the department's Internet web site posting confirming licensure. The current license certificate, or web site posting confirming licensure, of a licensee practicing in an institutional facility may be displayed in a central location.

Authority: AS 08.80.005 AS 08.80.030

Editor's note: The current posting confirming licensure can be found at the Internet web site of the Department of Commerce, Community, and Economic Development, Division of Corporations, Business and Professional Licensing: www.commerce.state.ak.us/occ/search3.htm.

12 AAC 52.991. DISCIPLINARY DECISION OR CONVICTION REPORTING REQUIREMENT. (a) A licensee shall report in writing to the board any disciplinary decision or conviction, including conviction of a felony or conviction of another crime that affects the applicant's or licensee's ability to practice competently and safely, issued against the licensee not later than 30 days after the date of the disciplinary decision or conviction.

(b) A licensed or registered facility shall report in writing to the board any disciplinary decision, including suspension or revocation by federal, state, or local government of a license currently or previously held by the applicant or facility for the manufacture or distribution of drugs or devices, including controlled substances, or any felony conviction under federal, state, or local law of an owner of the facility or of an employee of the facility.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.315
AS 08.80.005 AS 08.80.261 AS 08.80.460

12 AAC 52.992. INDEPENDENT ADMINISTRATION OF VACCINES AND RELATED EMERGENCY MEDICATIONS. (a) Before a pharmacist may independently administer a human vaccine or related emergency medication to a patient who does not have immunization contraindications as listed by the CDC, FDA, or manufacturer's package insert, or to a patient under a prescription drug order from a prescriber, the pharmacist

(1) must successfully complete a course accredited by the Accreditation Council for Pharmacy Education (ACPE) or a comparable course for pediatric, adolescent, and adult immunization practices that includes instruction on

(A) basic immunology, vaccine, and immunization protection;

(B) diseases that may be prevented by vaccination or immunization;

(C) current CDC immunization schedules;
(D) vaccine storage and management;
(E) informed consent;
(F) physiology and techniques for administration of immunizations;
(G) pre-immunization and post-immunization assessment and counseling;
(H) immunization reporting and records management; and
(I) identifying, responding to, documenting, and reporting adverse responses;

(2) must maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training;

(3) who has not administered a vaccine during the past 10 years must complete a course as described in (1) of this subsection before administering a vaccine; and

(4) must adhere to 12 AAC 52.320, including continuing education requirements under 12 AAC 52.320(e).

(b) A pharmacy from which a pharmacist administers a human vaccine or related emergency medication under this section

(1) must stock the following emergency medications in an emergency medication kit that is separate from the regular dispensing inventory, and that is carried by the pharmacist if providing off-site immunizations:
(A) oral and injectable diphenhydramine; and
(B) adult and pediatric auto-inject epinephrine devices, or injectable epinephrine;

(2) must maintain a policy and procedure manual detailing the immunization practices that must be followed; the manual must
(A) designate either the pharmacist-in-charge or an assigned vaccine coordinator who will be responsible for maintaining the policy and procedures manual;
(B) document that the policy and procedures manual has been reviewed and updated annually;
(C) address how vaccine related adverse reactions are to be reported to the CDC's and FDA's Vaccine Adverse Event Reporting System (VAERS);
(D) address proper vaccine storage, handling, and maintenance, including maintaining manufacturer-recommended temperatures during transportation of vaccines;
(E) address proper disposal of used or contaminated supplies;
(F) contain a written emergency protocol for handling accidental needlesticks and adverse reactions, including the administration of related emergency medications; and
(G) detail how records must be kept;

(3) must have access to the latest edition of the CDC's *Epidemiology and Prevention of Vaccine-Preventable Diseases* as a reference; and

(4) must display each pharmacist's certification of completing the immunization course described in (a)(1) of this section.

(c) Before administering an immunization or related emergency medication, a pharmacy intern must

(1) have completed an ACPE-accredited immunization course or other comparable course that meets the requirements of (a)(1) of this section;

(2) maintain certification and keep documentation in adult and pediatric cardiopulmonary resuscitation (CPR) and automated external defibrillator (AED) training; and

(3) be under the direct supervision of a pharmacist who has met the requirements of this chapter.

(d) A pharmacist or pharmacist intern administering a vaccine must offer the patient or the patient's agent the current vaccine information statement (VIS) issued by the CDC for each vaccine administered.

(e) A pharmacist or intern independently administering a vaccine must comply with 7 AAC 27.650.

(f) For purposes of this section, a pharmacist independently administers a human vaccine or related emergency medication if

(1) the pharmacist meets the requirements of this chapter and is the prescriber and administrator of the vaccine; or

(2) a pharmacist intern meeting the requirements of this chapter administers the vaccine, and the pharmacist supervising the pharmacist intern is the prescriber.

(g) Failure to comply with this section constitutes unprofessional conduct and is a basis for the imposition of disciplinary sanctions under AS 08.01.075.

(h) In this section,

(1) "CDC" means the United States Department of Health and Human Services, Centers for Disease Control and Prevention;

(2) "FDA" means the United States Food and Drug Administration.

Authority: AS 08.01.075 AS 08.80.030 AS 08.80.168 AS 08.80.261 AS 08.80.480

12 AAC 52.993. EXECUTIVE ADMINISTRATOR. The executive administrator may

(1) review and approve continuing education competency audits; audits that are not in compliance must be reviewed by a board member;

(2) attend state or national meetings or conferences on behalf of the board;

(3) work with the National Association of Boards of Pharmacy (NABP) on behalf of the board;

(4) work with the board chair and vice-chair in evaluation of questions posed to the board regarding AS 08.80 or 12 AAC 52;

(5) work with regulations specialist to draft and make regulatory amendment recommendations to 12 AAC 52 to the board.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.270

12 AAC 52.994. INDEPENDENT DISPENSING OF OPIOID OVERDOSE DRUGS BY PHARMACISTS. (a) A pharmacist may independently dispense an opioid overdose drug approved for use as an opioid overdose drug by the United States Food and Drug Administration. Before a pharmacist independently dispenses an opioid overdose drug to a recipient, the pharmacist shall

(1) in accordance with 12 AAC 52.340, complete a single training session that consists of one hour of continuing education specific to the use of an opioid overdose drug;

(2) question the recipient to determine if there are any known contraindications to opioid overdose drug usage for the potential user; and

(3) provide the recipient information about opioid overdose prevention, recognition, and response to opioid overdose drugs.

(b) A pharmacist may

(1) supply an opioid overdose drug as

(A) an intramuscular injection;

(B) an intranasal spray;

(C) an auto-injector; or

(D) any other product forms approved by the United States Food and Drug Administration; and

(2) recommend other optional items when appropriate, including

(A) alcohol pads;

(B) rescue breathing masks; or

(C) rubber gloves.

(c) When dispensing an opioid overdose drug

(1) the pharmacist shall

(A) label the drug in accordance with 12 AAC 52.480;

(B) ensure that the label includes appropriate directions; the label may not consist of the sole direction "use as directed";

(C) ensure that the label includes directions to call 911 or other available emergency services; and

(D) document the drug as a prescription in the medication record of the recipient in accordance with 12 AAC 52.450;

(2) the pharmacist may

(A) in accordance with 12 AAC 52.585, provide the recipient with counseling and information on the drug furnished, including

(i) dosing;

(ii) administration;

(iii) effectiveness;

(iv) adverse effects;

(v) storage conditions;

(vi) shelf life; and

(vii) safety;

(B) offer the recipient information or referrals to appropriate resources including information about addiction treatment, recovery services, or medication disposal resources, if the recipient indicates interest in that information.

(d) Nothing in this section restricts the ability of a pharmacist to furnish an opioid overdose drug by means of an authorized practitioner prescription under 12 AAC 52.460 or 12 AAC 52.490.

(e) In this section,

(1) "opioid overdose drug"

(A) has the meaning given in AS 08.80.168;

(B) includes naloxone hydrochloride;

(2) "recipient" means the person to whom an opioid overdose drug is furnished.

Authority: AS 08.80.030 AS 08.80.168 AS 08.80.480

12 AAC 52.995. DEFINITIONS. (a) In this chapter, unless the context requires otherwise,

(1) “ACPE” means Accreditation Council for Pharmacy Education;

(2) “approved program” means a continuing education activity that is a live program, home study, or other mediated instruction delivered by an approved or accredited provider;

(3) “approved provider” means an individual, institution, organization, association, corporation, or agency offering an approved program under 12 AAC 52.340 and is not an accredited provider;

(4) “authorized inspector” means a member of the board or an investigator with the division assigned occupational licensing functions in the department;

(5) "blood" means whole blood collected from a single donor and processed either for transfusion or further manufacturing;

(6) "blood component" means that part of blood separated by physical or mechanical means;

(7) "board" means the Alaska Board of Pharmacy;

(8) "care provider" means a person or organization that by the nature of experience and training is qualified, in the opinion of the board, to provide substance abuse counseling, rehabilitation, or related services to the public through established and recognized treatment programs;

(9) "consultant pharmacist" means a licensed pharmacist retained by written agreement with an institutional facility to consult on a routine basis with an institutional facility about the practice of pharmacy as it relates to that facility;

(10) "contact hour" means a unit of measure of educational credit that is equivalent to approximately 50 minutes of participation in an organized learning experience; a continuing education unit or "CEU" is equivalent to ten contact hours;

(11) "DEA" means the United States Drug Enforcement Administration;

(12) "department" means the Department of Commerce, Community, and Economic Development;

(13) "direct supervision" means supervision that insures adequate safety controls either by personal supervision or through a telepharmacy system;

(14) "home study" and "other mediated instruction" mean continuing education activities that are not conducted as live programs, including audio tapes, video tapes, television, computer assisted instruction, journal articles, or monographs;

(15) "institutional facility" means a

(A) hospital;

(B) long-term care facility, including a nursing home, convalescent home, or other related facility;

(C) mental health facility;

(D) rehabilitation center;

(E) psychiatric center;

(F) developmental disability center;

(G) drug abuse treatment center;

(H) family planning clinic;

(I) penal institution;

(J) hospice; or

(K) public health facility;

(16) "institutional pharmacy" means a pharmacy located in an institutional facility;

(17) "licensee" means a person who is licensed under AS 08.80 and this chapter;

(18) "live program" means an on-site continuing education activity, including a lecture, symposium, live teleconference, or workshop;

(19) "sterile pharmaceutical" means a drug dosage form free from living microorganisms (aseptic);

(20) "wholesale distribution" means distribution of prescription drugs to a person other than a consumer or patient, but does not include an activity described in 12 AAC 52.695;

(21) "central pharmacy" means a pharmacy providing remote pharmacy services through a telepharmacy system;

(22) "personal supervision" means supervision that includes visual or physical proximity to ensure adequate safety controls;

(23) "pharmacy" includes a central pharmacy and a remote pharmacy;

(24) "remote pharmacy" means a facility that provides pharmacy services, including the storage and distribution of prescription drugs, drug regimen review, and patient counseling through a telepharmacy system;

(25) "still image capture" means a specific image captured electronically from a video or other image capture device;

(26) "store and forward" means a video or still image record that is saved electronically for future review;

(27) "telepharmacy system" means a system under the direct supervision of a licensed pharmacist that monitors the dispensing and distribution of prescription drugs and provides for related drug use review and patient counseling services through a computer link and a video link with sound;

(28) "accredited provider" means an individual, institution, organization, association, corporation, or agency that is recognized by the ACPE as able to provide quality continuing education programs;

(29) "filling pharmacist" means a pharmacist participating in shared pharmacy services that processes or fills a prescription order for a patient;

(30) "filling pharmacy" means a pharmacy participating in shared pharmacy services that processes or fills a prescription order for a patient;

(31) "requesting pharmacist" means a pharmacist participating in shared pharmacy services that forwards a prescription order to another participating pharmacy or pharmacist to be processed or filled;

(32) "requesting pharmacy" means a pharmacy participating in shared pharmacy services that forwards a prescription order to another participating pharmacy to be processed or filled;

(33) "shared pharmacy services" means a system allowing the processing by a participating pharmacist or a pharmacy of a request from another participating pharmacist or pharmacy to enter or review a prescription drug order or process or fill a prescription drug order, including dispensing or distributing, drug utilization review, claims

adjudication, refill authorizations, therapeutic interventions, counseling, monitoring of drug therapy, and institutional order review;

(34) "dispenser" means a practitioner who delivers a controlled substance to an ultimate user or research subject under the lawful order of a practitioner; in this paragraph, "delivers" includes the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for delivery;

(35) "profile" means a compilation of data concerning a patient, a dispenser, a practitioner, or a controlled substance;

(36) "PDMP" means the prescription drug monitoring program's controlled substance prescription database;

(37) "moral turpitude" includes conduct that is considered contrary to community standards of justice, honesty, or good morals;

(38) "pharmacy technician who holds a national certification" means a pharmacy technician, licensed by the board, who obtains and maintains an active national certification through the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (NHA).

(b) In AS 08.80.315(3), "other persons or governmental agencies" include investigators for the department who are assigned to conduct investigations under AS 08.

(c) In AS 08.80.030(b)(7), "monitoring of drug therapy" means a review of the drug therapy regimen of patients by a pharmacist for the purpose of evaluating and rendering advice to the prescribing practitioner regarding adjustment of the regimen. "Monitoring of drug therapy" includes

(1) collecting and reviewing records of patient drug use histories;

(2) measuring and reviewing routine patient vital signs, including pulse, temperature, blood pressure, and respiration; and

(3) ordering and evaluating the results of laboratory tests relating to drug therapy, including blood chemistries and cell counts, drug levels in blood, urine, tissue, or other body fluids, and culture and sensitivity tests that are performed in accordance with a written protocol approved under 12 AAC 52.240.

(d) In AS 17.30.200 and 12 AAC 52.855 – 12 AAC 52.895, "practitioner" has the meaning given in AS 11.71.900.

(e) In 12 AAC 52.610 – 12 AAC 52.697, "facility manager" means the responsible manager who serves as the supervisor or manager and is responsible for ensuring the third-party logistics provider, wholesale drug distributor, or outsourcing facility is in compliance with all state and federal laws and regulations pertaining to the operations.

Authority: AS 08.80.005 AS 08.80.030 AS 08.80.157 AS 08.80.159 AS 11.71.900 AS 17.30.200 AS 17.30.900

CHAPTER 30.
CONTROLLED SUBSTANCES

Article

. . .

5. Controlled Substance Prescription Database (§§ 17.30.200)

. . .

CONTROLLED SUBSTANCE PRESCRIPTION DATABASE

Section

200. Controlled substance prescription database

Sec. 17.30.200. Controlled substance prescription database. (a) The controlled substance prescription database is established in the Board of Pharmacy. The purpose of the database is to contain data as described in this section regarding every prescription for a schedule II, III, or IV controlled substance under federal law dispensed in the state to a person other than under the circumstances described in (t) of this section.

(b) The pharmacist-in-charge of each licensed or registered pharmacy, regarding each schedule II, III, or IV controlled substance under federal law dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each practitioner who directly dispenses a schedule II, III, or IV controlled substance under federal law other than those dispensed or administered under the circumstances described in (t) of this section, shall submit to the board, by a procedure and in a format established by the board, the following information for inclusion in the database on at least a daily basis:

(1) the name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number or other appropriate identifier;

(2) the date of the prescription;

(3) the date the prescription was filled and the method of payment; this paragraph does not authorize the board to include individual credit card or other account numbers in the database;

(4) the name, address, and date of birth of the person for whom the prescription was written;

(5) the name and national drug code of the controlled substance;

(6) the quantity and strength of the controlled substance dispensed;

(7) the name of the drug outlet dispensing the controlled substance; and

(8) the name of the pharmacist or practitioner dispensing the controlled substance and other appropriate identifying information.

(c) The board shall maintain the database in an electronic file or by other means established by the board to facilitate use of the database for identification of

(1) prescribing practices and patterns of prescribing and dispensing controlled substances;

(2) practitioners who prescribe controlled substances in an unprofessional or unlawful manner;

(3) individuals who receive prescriptions for controlled substances from licensed practitioners and who subsequently obtain dispensed controlled substances from a drug outlet in quantities or with a frequency inconsistent with generally recognized standards of dosage for that controlled substance; and

(4) individuals who present forged or otherwise false or altered prescriptions for controlled substances to a pharmacy.

(d) The database and the information contained within the database are confidential, are not public records, are not subject to public disclosure, and may not be shared with the federal government. The board shall undertake to ensure the security and confidentiality of the database and the information contained within the database. The board may allow access to the database only to the following persons, and in accordance with the limitations provided and regulations of the board:

(1) personnel of the board regarding inquiries concerning licensees or registrants of the board or personnel of another board or agency concerning a practitioner under a search warrant, subpoena, or order issued by an administrative law judge or a court;

(2) authorized board personnel or contractors as required for operational and review purposes;

(3) a licensed practitioner having authority to prescribe controlled substances or an agent or employee of the practitioner whom the practitioner has authorized to access the database on the practitioner's behalf, to the extent the information relates specifically to a current patient of the practitioner to whom the practitioner is prescribing or considering prescribing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(4) a licensed or registered pharmacist having authority to dispense controlled substances or an agent or employee of the pharmacist whom the pharmacist has authorized to access the database on the pharmacist's behalf, to the extent the information relates specifically to a current patient to whom the pharmacist is dispensing or considering dispensing a controlled substance; the agent or employee must be licensed or registered under AS 08;

(5) federal, state, and local law enforcement authorities may receive printouts of information contained in the database under a search warrant or order issued by a court establishing probable cause for the access and use of the information;

(6) an individual who is the recipient of a controlled substance prescription entered into the database may receive information contained in the database concerning the individual on providing evidence satisfactory to the board that the individual requesting the information is in fact the person about whom the data entry was made and on payment of a fee set by the board under AS 37.10.050 that does not exceed $10;

(7) a licensed pharmacist employed by the Department of Health and Social Services who is responsible for administering prescription drug coverage for the medical assistance program under AS 47.07, to the extent that the information relates specifically to prescription drug coverage under the program;

(8) a licensed pharmacist, licensed practitioner, or authorized employee of the Department of Health and Social Services responsible for utilization review of prescription drugs for the medical assistance program under AS 47.07, to the extent that the information relates specifically to utilization review of prescription drugs provided to recipients of medical assistance;

(9) the state medical examiner, to the extent that the information relates specifically to investigating the cause and manner of a person's death;

(10) an authorized employee of the Department of Health and Social Services may receive information from the database that does not disclose the identity of a patient, prescriber, dispenser, or dispenser location, for the purpose of identifying and monitoring public health issues in the state; however, the information provided under this paragraph may include the region of the state in which a patient, prescriber, and dispenser are located and the specialty of the prescriber; and

(11) a practitioner, pharmacist, or clinical staff employed by an Alaska tribal health organization, including commissioned corps officers of the United States Public Health Service employed under a memorandum of agreement; in this paragraph, "Alaska tribal health organization" has the meaning given to "tribal health program" in 25 U.S.C. 1603.

(e) The failure of a pharmacist-in-charge or a pharmacist to register or submit information to the database as required under this section is grounds for the board to take disciplinary action against the license or registration of the pharmacy or pharmacist. The failure of a practitioner to register or review the database as required under this section is grounds for the practitioner's licensing board to take disciplinary action against the practitioner.

(f) The board may enter into agreements with (1) dispensers in this state that are not regulated by the state to submit information to and access information in the database, and (2) practitioners in this state to access information in the database, subject to this section and the regulations of the board. The board shall prohibit a dispenser that is not regulated by the state from accessing the database if the dispenser has accessed information in the database contrary to the limitations of this section, discloses information in the database contrary to the limitations of this section, or allows unauthorized persons access to the database.

(g) The board shall promptly notify the president of the senate and the speaker of the house of representatives if, at any time after September 7, 2008, the federal government fails to pay all or part of the costs of the controlled substance prescription database.

(h) An individual who has submitted information to the database in accordance with this section may not be held civilly liable for having submitted the information. Dispensers or practitioners may not be held civilly liable for damages for accessing or failing to access the information in the database.

(i) A person who has reason to believe that prescription information from the database has been illegally or improperly accessed shall notify an appropriate law enforcement agency.

(j) The board shall notify any person whose prescription information from the database is illegally or improperly accessed.

(k) In the regulations adopted under this section, the board shall provide

(1) that prescription information in the database shall be purged from the database after two years have elapsed from the date the prescription was dispensed;

(2) a method for an individual to challenge information in the database about the individual that the person believes is incorrect or was incorrectly entered by a dispenser;

(3) a procedure and time frame for registration with the database;

(4) that a practitioner review the information in the database to check a patient's prescription records before dispensing, prescribing, or administering a schedule II or III controlled substance under federal law to the patient; the regulations must provide that a practitioner is not required to review the information in the database before dispensing, prescribing, or administering

(A) a controlled substance to a person who is receiving treatment

(i) in an inpatient setting;

(ii) at the scene of an emergency or in an ambulance; in this sub-subparagraph, "ambulance" has the meaning given in AS 18.08.200;

(iii) in an emergency room;

(iv) immediately before, during, or within the first 48 hours after surgery or a medical procedure;

(v) in a hospice or nursing home that has an in-house pharmacy; or

(B) a nonrefillable prescription of a controlled substance in a quantity intended to last for not more than three days.

(*l*) A person

(1) with authority to access the database under (d) of this section who knowingly

(A) accesses information in the database beyond the scope of the person's authority commits a class A misdemeanor;

(B) accesses information in the database and recklessly discloses that information to a person not entitled to access or to receive the information commits a class C felony;

(C) allows another person who is not authorized to access the database to access the database commits a class C felony;

(2) without authority to access the database under (d) of this section who knowingly accesses the database or knowingly receives information that the person is not authorized to receive under (d) of this section from another person commits a class C felony.

(m) To assist in fulfilling the program responsibilities, performance measures shall be reported to the legislature annually. Performance measures

(1) may include outcomes detailed in the federal prescription drug monitoring program grant regarding efforts to

(A) reduce the rate of inappropriate use of prescription drugs by reporting education efforts conducted by the Board of Pharmacy;

(B) reduce the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit;

(C) increase coordination among prescription drug monitoring program partners;

(D) involve stakeholders in the planning process;

(2) shall include information related to the

(A) security of the database; and

(B) reductions, if any, in the inappropriate use or prescription of controlled substances resulting from the use of the database.

(n) A pharmacist who dispenses or a practitioner who prescribes, administers, or directly dispenses a schedule II, III, or IV controlled substance under federal law shall register with the database by a procedure and in a format established by the board.

(o) The board shall promptly notify the State Medical Board, the Board of Nursing, the Board of Dental Examiners, the Board of Examiners in Optometry, and the Board of Veterinary Examiners when a practitioner registers with the database under (n) of this section.

(p) The board is authorized to provide unsolicited notification to a pharmacist, practitioner's licensing board, or practitioner if a patient has received one or more prescriptions for controlled substances in quantities or with a frequency inconsistent with generally recognized standards of safe practice. An unsolicited notification to a practitioner's licensing board under this section

(1) must be provided to the practitioner;

(2) is confidential;

(3) may not disclose information that is confidential under this section;

(4) may be in a summary form sufficient to provide notice of the basis for the unsolicited notification.

(q) The board shall update the database on at least a daily basis with the information submitted to the board under (b) of this section.

(r) The Department of Commerce, Community, and Economic Development shall

(1) assist the board and provide necessary staff and equipment to implement this section; and

(2) establish fees for registration with the database by a pharmacist or practitioner required to register under (n) of this section so that the total amount of fees collected by the department equals the total operational costs of the database minus all federal funds acquired for the operational costs of the database; in setting the fee levels, the department shall

(A) set the fees for registration with the database so that the fees are the same for all practitioners and pharmacists required to register; and

(B) consult with the board to establish the fees under this paragraph.

(s) Notwithstanding (p) of this section, the board may issue to a practitioner periodic unsolicited reports that detail and compare the practitioner's opioid prescribing practice with other practitioners of the same occupation and similar specialty. A report issued under this subsection is confidential and the board shall issue the report only to a practitioner. The board may adopt regulations to implement this subsection. The regulations may address the types of controlled substances to be included in an unsolicited report, the quantities dispensed, the medication strength, and other factors determined by the board.

(t) A practitioner or a pharmacist is not required to comply with the requirements of (a) and (b) of this section if a controlled substance is

(1) administered to a patient at

(A) a health care facility; or

(B) a correctional facility;

(2) dispensed to a patient for an outpatient supply of 24 hours or less at a hospital

(A) inpatient pharmacy; or

(B) emergency department.

(u) In this section,

(1) "board" means the Board of Pharmacy;

(2) "database" means the controlled substance prescription database established in this section;

(3) "knowingly" has the meaning given in AS 11.81.900;

(4) "opioid" includes the opium and opiate substances and opium and opiate derivatives listed in AS 11.71.140 and 11.71.160;

(5) "pharmacist-in-charge" has the meaning given in AS 08.80.480.

General Requirements.

(a) Each pharmacy is of sufficient size to allow for the safe and proper storage of prescription drugs and for the safe and proper compounding and/or preparation of prescription drug orders.

(b) There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(c) The prescription department and all areas where drugs are stored are well lighted, well ventilated, dry, and maintained in a clean and orderly condition. Walls, floors, ceilings, and windows are clean and in general good repair and order.

(d) Each pharmacy has a sink with hot and cold running water within the pharmacy and maintained in a sanitary condition.

(e) There are refrigeration facilities with a thermometer in the prescription department for the proper storage of drugs requiring refrigeration. Temperatures in the refrigerator are maintained within United States Pharmacopeia standards.

(f) The temperature of the pharmacy is maintained within a range compatible with the proper storage of drugs.

Equipment and Supplies.

(a) All pharmacies have in their possession the equipment and supplies necessary to compound, dispense, label, administer and distribute drugs and devices. The equipment is in good repair and is available in sufficient quantity to meet the needs of the practice of pharmacy conducted therein.

(b) All equipment is kept in a clean and orderly manner. Equipment used in the compounding or preparation of prescription drug orders (counting, weighing, measuring, mixing, stirring, and molding equipment) is clean and in good repair.

Library. A reference library is maintained which includes the following:

(1) A current copy (hard-copy or electronic media access) of the Alaska Pharmacy Statutes and Regulations.

(2) At least one current or updated reference (hard-copy or electronic media access) from each of the following categories:

(A) Patient information – examples are;

(i) USP Dispensing Information; or

(ii) Patient Drug Facts; or

(iii) reference text or information leaflets which provide patient information.

(B) General information – examples are;

(i) Facts and Comparisons; or

(ii) USP Dispensing Information, Volume I (Drug Information for the Healthcare Provider); or

(iii) Remington's Pharmaceutical Sciences.

(C) Clinical Information – examples are;

(i) AHFS Drug Information; or

(ii) Micromedex; or

(iii) Clinical Pharmacology; or

(iv) reference material pertinent to the practice setting.

(3) The telephone number of the nearest poison control center is readily available.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines on facilities, reference materials, equipment, supplies and other matters. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.400.

STERILE PHARMACEUTICALS
February 2008

Scope and Purpose.

The purpose of this pamphlet is to provide standards for the preparation, labeling, and distribution of sterile products by pharmacies, pursuant to or in anticipation of a prescription drug order. These standards are intended to apply to all sterile products, notwithstanding the location of the patient (eg. home, hospital, extended care facility, hospice, practitioner's office).

Definitions.

(a) "Biological Safety Cabinet" – a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, according to National Sanitation Foundation (NSF) Standard 49.

(b) "Class 100 Environment" – an atmospheric environment which contains less than 100 particles 0.5 microns in diameter per cubic foot of air, according to Federal Standard 209D.

(c) "Cytotoxic" – a pharmaceutical that has the capability of killing living cells.

(d) "Parenteral" – a sterile preparation of drugs for injection through one or more layers of the skin.

(e) "Sterile Pharmaceutical" – dosage form free from living micro-organisms (aseptic).

Policy and Procedure Manual.

(a) A policy and procedure manual is prepared and maintained for the compounding, dispensing, and delivery of sterile pharmaceutical drug orders. The manual is reviewed and revised as necessary on an annual basis by the pharmacist-in-charge and is available for inspection at the pharmacy.

(b) The manual includes policies and procedures, as applicable, for:

(1) Clinical services;
(2) Sterile product handling, preparation, dating, storage and disposal;
(3) Major and minor spills of cytotoxic agents;
(4) Disposal of unused supplies and medications;
(5) Drug destruction and returns;
(6) Drug dispensing;
(7) Drug labeling;
(8) Duties and qualifications for professional and nonprofessional staff;
(9) Equipment use and maintenance;
(10) Handling of infectious waste pertaining to drug administration;
(11) Infusion devices and drug delivery systems;
(12) Training and orientation of professional and non-professional staff commensurate with the services provided;
(13) Dispensing of investigational medications;
(14) Quality control and quality assurance;
(15) Recall procedures;
(16) Infection control;
(17) Suspected contamination of sterile products;
(18) Orientation of employees to sterile technique;
(19) Sanitation;
(20) Security; and
(21) Transportation.

Physical Requirements.

(a) The pharmacy designates an area for the preparation of sterile products that is functionally separate from areas for the preparation of non-sterile products and is constructed to minimize traffic and airflow disturbances. It is used only for the preparation of these specialty products. It is of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy preparing parenteral products has:

(1) Appropriate environmental control devices capable of maintaining at least a Class 100 environment condition in the workspace where critical objects are exposed and critical activities are performed; furthermore, these devices are capable of maintaining Class 100 environments during normal activity;

(2) When cytotoxic drug products are prepared, appropriate environmental control also includes appropriate biological safety cabinets;

(3) Sink with hot and cold running water which is convenient to the compounding area for the purpose of hand washing prior to compounding;

(4) The designated area shall have hard cleanable surfaces, walls, floors and ceilings;

(5) Appropriate disposal containers for used needles, syringes, etc. and if applicable, for cytotoxic waste from the preparation of chemotherapy agents and infectious wastes from patient's homes;

(6) Refrigerator/freezer with thermometer;

(7) Temperature controlled delivery container, if appropriate;

(8) Infusion devises, if appropriate;

(9) Supplies adequate to maintain an environment suitable for the aseptic preparation of sterile products.

(c) Laminar flow hood certification (or clean room certification, if applicable) are conducted at least every six months by an independent contractor according to Federal Standard 209B or National Sanitation Foundation 49 for operational efficiency. These reports are maintained for at least two years. In addition, prefilters are replaced on a regular basis and the replacement date documented.

(d) The pharmacy has current reference materials related to sterile products. These reference materials will contain information on stability, incompatibilities, preparation guidelines, and the handling of chemotherapy drug products.

Personnel.

(a) All personnel participating in the preparation and/or dispensing of compounded sterile pharmaceuticals are trained in this specialized function, including the principles of aseptic technique. All duties and responsibilities of personnel are consistent with their training and experience.

(b) Pharmacies providing parenteral products to non-hospitalized patients have a pharmacist accessible twenty-four hours per day to respond to patient's and other health professional's questions and needs.

Drug Distribution and Control.

(a) In addition to labeling required for all dispensed prescription drug orders, the labeled container of a sterile pharmaceutical bears the expiration date of the preparation based upon published data.

(b) Delivery Service. The pharmacist-in-charge assures the environmental control of all products shipped. Therefore, any compounded sterile pharmaceutical is shipped or delivered to a patient in appropriate temperature controlled (as defined by United States Pharmacopeia Standards) delivery containers and stored appropriately in the patient's home or outpatient location.

(c) Disposal of Infectious/Hazardous Waste. The pharmacist-in-charge is responsible for assuring there is a system for the disposal of cytotoxic waste and infectious waste in a manner so as not to endanger the public health.

(d) Emergency Kit. When sterile pharmaceuticals are provided to home care patients, the pharmacy may supply the licensed nurse with emergency drugs, if the prescribing practitioner has authorized the use of these drugs by a protocol for use in an emergency situation (e.g. anaphylactic shock).

Cytotoxic Drugs.

The following additional requirements are necessary for those pharmacies that prepare cytotoxic drugs to assure the protection of the personnel involved:

(a) All cytotoxic drugs are compounded within a vertical flow, Class II, Biological Safety Cabinet. Policy and procedures are developed for the cleaning of the laminar airflow hood between compounding cytotoxic drugs and other parenteral products, if applicable.

(b) Protective apparel is worn by personnel compounding cytotoxic drugs. This includes disposable gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding cytotoxic drugs are used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of cytotoxic waste complies with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of cytotoxic agents are developed and included in the policy and procedure manual.

(f) Prepared doses of cytotoxic drugs are dispensed, labeled with proper precautions, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

Patient Training.

If appropriate, the Pharmacist demonstrates or documents the patient's training and competency in managing the type of therapy provided by the Pharmacist to the patient in the home environment. A pharmacist is involved in the patient training process in any area that relates to drug compounding, labeling, storage, stability, or incompatibility. The Pharmacist is responsible for seeing the patient's competency in the above areas is reassessed on an ongoing basis.

Quality Control and Quality Assurance Procedures.

(a) Quality Control. There is a documented, ongoing quality control program that monitors and evaluates personnel performance, equipment and facilities. Procedures are in place to assure the pharmacy is capable of consistently preparing pharmaceuticals which are sterile and stable. Quality control procedures include, but are not limited to, the following:

(1) recall procedures;

(2) storage and dating;

(3) documentation of appropriate functioning of refrigerator, freezer, and other equipment;

(4) documentation of aseptic environmental control device certification and the regular replacement of prefilters;

(5) a process to evaluate and confirm the quality of the prepared pharmaceutical product; and

(6) if bulk compounding of parenteral solutions is performed utilizing non-sterile chemicals, extensive end product testing is documented prior to the release of the product from quarantine. This process includes appropriate tests for particulate matter and pyrogens.

(b) Quality Assurance.

(1) There is a documented, ongoing quality assurance program for monitoring and evaluating personnel performance and patient outcomes to assure efficient drug delivery, patient safety, and positive patient outcomes.

(2) There is documentation of quality assurance audits at regular, planned intervals which may include infection control, sterile technique, delivery systems/times, order transcription accuracy, drug administration systems, adverse drug reactions, and drug therapy appropriateness.

(3) A plan for corrective action of problems identified by quality assurance audits is developed which includes procedures for the documentation of identified problems and action taken.

(4) A periodic evaluation of the effectiveness of the quality assurance activities is completed and documented.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist that prepares or dispenses sterile pharmaceuticals. Professional conduct by a licensee includes adherence to these guidelines. See 12 AAC 52.430.

(a) A pharmacist may compound drugs in limited quantities before receiving a valid prescription drug order if the pharmacist has a historical basis of valid prescription drug orders generated solely within an established relationship between the pharmacist, a patient, and a prescribing practitioner for the amount of drugs compounded. Compounding drugs in an amount above that for which there is a historical basis is considered manufacturing.

(b) Compounding includes the preparation

(1) according to a prescription drug order of drugs or devices that are not commercially available;

(2) of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist.

(c) When a compounded product is to be substituted for a commercially available product, both the patient and the prescribing practitioner must authorize the use of the compounded product. The pharmacist shall document these authorizations on the prescription drug order or in the computerized patient medication record. The prescribing practitioner's authorization is in addition to signing to permit substitution on a prescription drug order or advising verbally that substitution is permitted. The reconstitution of commercially available products according to the manufacturer's guidelines is permissible without notice to the prescribing practitioner.

(d) A pharmacist may not offer compounded drug products to prescribing practitioners, pharmacists, or pharmacies for resale except in the course of professional practice for a prescribing practitioner to administer to an individual patient. The distribution of inordinate amounts of compounded products without a relationship between the pharmacist and the prescribing practitioner and patient is considered manufacturing.

(e) A pharmacist may receive, store, and use drug substances for compounding prescriptions that meet official compendia requirements. A pharmacist shall use the pharmacist's professional judgment to receive, store, and use drug substances for compounding prescriptions not found in official compendia.

PERSONNEL

A pharmacist engaging in compounding shall maintain proficiency through current awareness and training. Continuing education should include training in the art and science of compounding and the rules and regulations of compounding.

COMPOUNDING FACILITIES

(a) A pharmacy engaging in compounding shall have a specifically designated and adequate area for the orderly compounding of prescriptions that is maintained in a good state of repair and for the placement of materials and equipment. There is a minimum of three linear feet by a minimum of 18 inches in depth of counter working space for each pharmacist or intern compounding or filling prescriptions at the same time.

(b) Bulk medications and other chemicals or materials used in the compounding of medications must be stored in adequately labeled containers in a clean, dry, and temperature controlled area or, if required, under proper refrigeration.

(c) Adequate lighting and ventilation must be provided in all drug compounding areas. Potable water must be supplied under continuous positive pressure in a plumbing system free of defects that could contribute contamination to any compounded drug product. Adequate washing facilities, easily accessible to the compounding area of the pharmacy must be provided. The facilities must include hot and cold water, soap or detergent, and air-driers or single use towels.

(d) The area used for the compounding of drugs must be maintained in a clean and sanitary condition. It must be free of infestation by insects, rodents, and other vermin. Trash must be held and disposed of in a timely and sanitary manner. Sewage and other refuse must be disposed of in a safe and sanitary manner.

(e) If drug products with special precautions for contamination, such as penicillin, are involved in a compounding procedure, appropriate measures, including either the dedication of equipment or meticulous cleaning of contaminated equipment prior to its use for the preparation of other drugs, must be used in order to prevent cross-contamination.

RECORDS AND REPORTS

(a) A pharmacist shall keep records of all compounded products for two years. The records must be readily available for authorized inspection at the pharmacy.

(b) A pharmacist shall ensure that there are formulas maintained electronically or manually. A formula must include ingredients, amounts, methodology and equipment, if needed, and special information regarding sterile compounding.

(c) A pharmacy engaging in compounding must have written procedures for the compounding of drugs to assure that the finished products have the identity, strength, quality, and purity they are represented to possess. The procedures must include a listing of the components, their amounts in weight or volume, the order of component mixing, and a description of the compounding process. The procedures must list all equipment and utensils and the container or closure system relevant to the sterility and stability of the intended use of the drug. The procedures must be followed in the execution of the drug compounding procedure.

(d) A pharmacist shall accurately weigh, measure, or subdivide as appropriate the components for drug product compounding. The compounding pharmacist shall check these operations at each stage of the compounding process to ensure that each weight or measure is correct as stated in the written compounding procedures. If a component is transferred from the original container to another container, the new container must be identified with the component name and the weight or measure.

(e) To assure the reasonable uniformity and integrity of compounded drug products, written procedures must be established and followed that describe the tests or examinations to be conducted on the product compounded. The control procedures must be established to monitor the output and to validate the performance of those compounding processes that include the following when appropriate:

(1) capsule weight variation;

(2) adequacy of mixing to assure uniformity and homogeneity;

(3) clarity, completeness, or pH of solutions;

(f) A pharmacy engaging in compounding shall establish and follow appropriate written procedures designed to prevent microbiological contamination of compounded drug products purporting to be sterile. The procedures must include validation of any sterilization process.

(g) For the purpose of compounding in quantities larger than required for immediate dispensing by a prescriber or for future dispensing upon prescription, a pharmacy shall maintain records that include

(1) the date of preparation;

(2) the lot numbers – the lot numbers may be the manufacturer's lot numbers or new numbers assigned by the pharmacy. If a lot number is assigned by the pharmacy, the pharmacy shall record the original manufacturer's lot numbers and expiration dates, if known. If the original manufacturer's lot numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the components;

(3) the expiration date of the finished product. This date may not exceed 180 days or the shortest expiration date of any component in the finished product unless a longer date is supported by stability studies in the same type of packaging as furnished to the prescriber or to be stored in until dispensing. Shorter dating than set forth in this subsection may be used if it is deemed appropriate in the professional judgment of the responsible pharmacist;

(4) the signature or initials of the pharmacist performing the compounding;

(5) initials of the person preparing each process;

(6) initials of the pharmacist supervising each process;

(7) a formula for the compounded product maintained in a readily retrievable form;
(8) the name of the manufacturer of the raw materials;

(9) the quantity in units of finished products or grams of raw materials; and

(10) the package size and the number of units prepared.

(h) "Component" means any ingredient intended for use in the compounding of a drug product, including those that may not appear in the product.

This pamphlet is prepared by the Alaska Board of Pharmacy to establish guidelines for a pharmacy or pharmacist on compounding practices. Professional conduct by a licensee includes adherence to these guidelines.
See 12 AAC 52.440.